DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY -6 1997

Mr. Jeffrey R. Mannion
Regulatory Affairs Associate
AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury, New York 12804

Re: K964034
Transjugular Access Set
Regulatory Class: II (two)
Product Code: DYB
Dated: February 4, 1997
Received: February 5, 1997

Dear Mr. Mannion:

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 (for the indications for use stated in the enclosure) 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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in

regulatory action. In addition, 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 might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K964034

Device Name: Transjugular Access Set

Indications For Use:

The ANGIODYNAMICS, Inc. Transjugular Liver Access Set is intended to be used for transjugular liver access during diagnostic and interventional procedures.

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510(k) Numbe

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
Neurological Devices
510(k) Number K964034

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 1 or Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(K) ROUTE SLIP

510(k) NUMBER K964034 PANEL CV DIVISION DCRND BRANCH ICDG

TRADE NAME TRANSJUGULAR ACCESS SET

COMMON NAME CATHETER INTRODUCER

PRODUCT CODE DYB INTRODUCER, CATHETER

APPLICANT ANGIODYNAMICS, INC.
SHORT NAME ANGIODYNAMICS
CONTACT BRIAN KUNST
DIVISION
ADDRESS 603 QUEENSBURY AVE.
QUEENSBURY, NY 12804
PHONE NO. (518) 798-1215 FAX NO. (518) 798-3625

MANUFACTURER ANGIODYNAMICS, INC. REGISTRATION NO. 1319211
COSMED II 1222273

DATE ON SUBMISSION 30-SEP-96 DATE DUE TO 510(K) STAFF 22-DEC-96

DATE RECEIVED IN ODE 08-OCT-96 DATE DECISION DUE 06-JAN-97

DECISION __ DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	04-FEB-97	05-FEB-97	21-APR-97	06-MAY-97	

CORRESPONDENCE	SENT	DUE BACK	
C001	06-JAN-97	05-FEB-97	HOLD LETTER

Is this 510(k) identified as a Class III device ____YES ____NO

SE
MAY 6 1997

Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Donna Buckley

Subject: 510(k) Number K964034/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☒NO
Is this device subject to the Tracking Regulation?	☐YES	☒NO
Was clinical data necessary to support the review of this 510(k)?	☒YES	☐NO
Is this a prescription device?	☒YES	☐NO
Was this 510(k) reviewed by a Third Party?	☐YES	☒NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☒Enclosed
(required for originals received 3-14-95 and after)

☐A 510(k) summary OR ☒A 510(k) statement

☐ The required certification and summary for class III devices N/A

☒ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

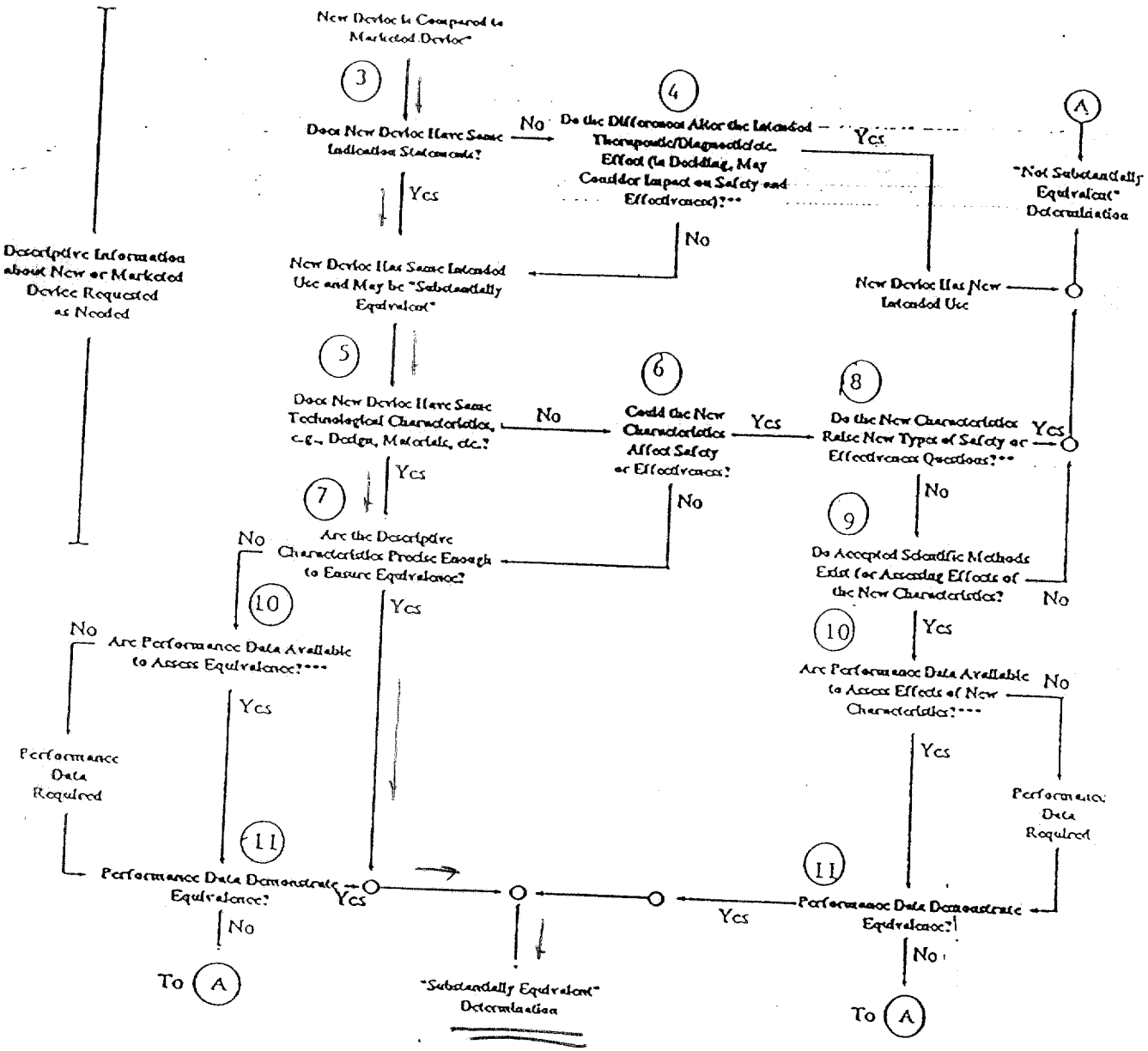
74 DYB, Class II

Review: Judy Anderson (Branch Chief) Signatory Reviewer — ICDG (Branch Code) — 5/5/97 (Date)

Final Review: I am A Rn for Thomas Callahan, PhD (Division Director) — 5/6/97 (Date)

Revised: 11-20-96

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

DATE: April 11, 1997

TO: File K964034/S1

FROM: Donna C. Buckley
Mechanical Engineer, FDA/CDRH/ODE/DCRND/ICDG

SUBJECT: 510(k) Review of Transjugular Access Kit (catheter introducer) -- Angiodynamics

CONTACT: Brian Kunst -- (518) 798-1215 ext.190; FAX (518) 798-3625

DECISION: **SUBSTANTIALLY EQUIVALENT**
74 DYB -- catheter introducer -- 870.1340 -- class II

The sponsor has responded to our January 6, 1997, deficiency letter. In that letter, several questions were asked in order to clarify the device indications and to assess whether the functional characteristics of the device are similar to those of the predicate device.

The device is indicated for percutaneous transjugular access during diagnostic and/or therapeutic interventional procedures. The examples of devices provided in the labeling that are intended for use following liver access are biliary drainage catheters, balloon catheters, and biopsy needles. Since I am unfamiliar with the use of these devices, I requested input from Dr. Daniel Schultz (DRAERD) regarding the device indications and functional characteristics. In response, Dr. Schultz spoke with Anthony Venbrux, Associate Professor of Radiology at Johns Hopkins University, regarding the clinical use of this type of device. Dr. Schultz apprised me of the discussion with Dr. Venbrux and indicated that the stated indications are generally consistent with the current use of the predicate device. For example, an intravascular approach to liver biopsy may be used with patients where a percutaneous liver biopsy would be too hazardous. Also, an intravascular approach may be taken to implant a stent that creates a shunt between the hepatic and portal systems in order to lower the portohepatic pressure gradient. (See attached excerpts and references). Following discussion with several reviewers (and very limited research), I believe that the indications provided in this submission are consistent with the current uses of the predicate.

Since the predicate device, the Cook Rosch-Uchida transjugular liver access set, was declared to be a "modified preamendment" device, no predicate engineering data are on file. Because of the lack of predicate data and the identity of "critical" engineering characteristics of such a device, I believe that the collection of data on the catheter system delivery characteristics (e.g., flexibility, tracking, tensile strength, etc.) and needle characteristics (e.g., sharpness, surface characteristics, mechanical properties, etc.) may not be sufficient to evaluate device safety or efficacy in the absence of both animal studies and clinical data. For this reason, I called Mr. Kunst to discuss my concerns and inquired whether Angiodynamics anticipated collecting animal data or clinical data on the device prior to releasing it to market. Mr. Kunst reported that they had not anticipated collecting animal

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data in support of the 510(k) submission, however, he agreed to provide me with an article from the Journal of Vascular and Interventional Radiology (fax: 4/24) that reported the clinical use of a device "very similar" to the device under review. The article reported on the use of a particular transjugular liver access set in the placement of Wallstents in 75 patients during transjugular intrahepatic potosystemic shunt (TIPS) procedures. The device referred to in the article was directly compared to the predicate and was reported to "enhance the ability to avoid intervening vital structures and potentially lessen the effect of errant punctures, overcome parenchymal tract resistance in extremely cirrhotic livers, and prevent buckling into the right atrium." (Note: No direct comparisons of clinical data were made to support these conclusions.)

Given the description of the device in the article, I was unable to directly compare the device components to those of the device under review. I called Mr. Kunst and reported that animal data would be essential if he was unable to demonstrate that the devices were either identical or that the differences between them were clinically inconsequential. I received a fax on 4/25 (attached) that compared the components. After review of the supplied information, I believe the device differences to be minor and the referenced clinical information to be supportive of device function. I believe that additional engineering data will not necessarily add new information.

I believe that the prior deficiencies have been adequately addressed and I recommend that this device be found substantially equivalent to 74 DYB (catheter introducer), a class II device.

Donna Buckley 4/28/97

Daniel Schultz, M. D. 4/28/97
(concurrence: evaluation of indications and general function)

Concur JDonnelan 5/5/97

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the syringe used for anesthetic infiltration, with a small amount of anesthetic left in the syringe. The needle is inserted through a small hole in the skin down to the lesion, which has been visualized. It is then rapidly thrust into the lesion while suction is applied to the syringe, and then it is rapidly withdrawn. Fine-needle aspiration is most often done under ultrasonographic or CT control, so that focal lesions can be sampled. Because the procedure elicits little pain, multiple sticks can be employed, each in a slightly different direction. The material aspirated consists of small fragments of tissue or isolated cells or groups of cells. The aspirate can be smeared on a slide, ejected into appropriate fixatives, or placed in tissue culture media.

Most of the diagnostic interest has been in confirming the presence of a primary hepatocellular carcinoma[51–53] or a hepatoblastoma[54] (Chapter 128). For this purpose, new criteria had to be established for the cytologic diagnosis[55, 56] and the differentiation of primary carcinoma from metastases in the liver.[57] Immunocytochemical methods have also been applied to these specimens to identify the site of origin of a carcinoma; alpha-fetoprotein and other oncofetal markers, intermediate filaments of the cytoskeleton, and hepatocellular markers are used.[58] Special cytologic and cytochemical techniques that can be applied to fine-needle samples are described later in this chapter.

Comparisons have been made between histologic and cytologic methods, and both had about equal diagnostic accuracy; therefore, both are recommended.[59–61] When a carcinoma is suspected but not diagnosed with guided fine-needle biopsy, a core biopsy is recommended to confirm the presence of a benign lesion.[62] Hemangiomas can be recognized cytologically[63, 64] and represent a condition that should not indicate a core biopsy. Fine-needle aspirations have also been used to diagnose tumors of the biliary tree and pancreas causing obstructive jaundice.[65, 66] Percutaneous transhepatic catheterization under fluoroscopic control has been suggested as the route to introduce the fine needle to avoid seeding malignant cells along the biopsy track.[67] Washings from the needle and from biopsy specimens have been used for cytologic examinations.[68–70] CT guidance[71] has been compared with ultrasonographic guidance, and both seem to be equally effective, although the former was better in the presence of ascites.[72]

Transjugular Liver Biopsy

A completely intravascular approach has been used when a liver biopsy is indicated but the condition of the patient is such that a percutaneous biopsy would be too hazardous.[73–77] The biopsy is best performed by passing a Tru-Cut–style needle inside a 45-cm cardiac catheter into the jugular vein through the superior vena cava directly into a hepatic vein. This must be done under fluoroscopic control and with electrocardiographic monitoring. After the catheter is wedged into a hepatic vein tributary, the needle is thrust into the parenchyma and is triggered via a coaxial cable. Samples obtained with this Tru-Cut–style needle are almost the same size as percutaneous biopsy specimens. The number of instances in which such a procedure is necessary seems to be small. Often, fine-needle aspiration or laparoscopy is simpler, safer, and less costly in providing the needed information. The femoral vein can also be used for transvenous biopsy with a small biopsy forceps.[78]

Laparoscopic Biopsy

Direct vision is sometimes necessary to sample focal lesions detected by ultrasonography or CT or those that are suspected and not seen by imaging. Laparoscopy, in experienced hands, provides such a technique. It can be used to identify primary[79] or metastatic[80] carcinomas or even the transition of chronic hepatitis to cirrhosis.[81] The biopsy is best done percutaneously with a needle, which can be guided by the laparoscopist into the site to be examined. At the same time, a biopsy specimen can be obtained from the uninvolved liver. The Tru-Cut or the Menghini needle can be used, or multiple aspirations with the fine needle can be performed. Morbidity after laparoscopy is minimal. Laparoscopic control has been compared with and preferred to ultrasonographic[82] and CT[83] control.

WHEN NOT TO DO A LIVER BIOPSY

Few contraindications can be listed for liver biopsy. Each experienced operator has a personal set of contraindications, which are often based on personal experience. What follows represents the preferences and prejudices of the authors. The one contraindication most universally agreed on is a bleeding tendency, but the definitions of bleeding tendency vary. A prothrombin time greater than 5 to 6 s from control values is too long for biopsy, although some centers refuse to perform a biopsy if the prothrombin time is 3 to 4 s greater than control values. Postbiopsy bleeding has almost always occurred in patients with normal prothrombin times. Platelet counts less than 50,000 to 60,000/mm^3 are universally considered too low for biopsy, and some centers require more than 75,000 to 80,000/mm^3. Partial thromboplastin time need not be tested in adults with no history of a bleeding diathesis. The levels of clotting factors can be corrected with fresh frozen plasma and platelet transfusions, but rarely does this have to be done, except for some vascular tumors.[84] A biopsy in a patient with greatly disturbed blood coagulation is not likely to yield information not already known and critical to the care of that patient.

Pleural effusion, empyema, pneumothorax, extensive ascites, and peritonitis are reasons to postpone a biopsy until these problems are corrected. Biopsy of cysts and hemangiomas should not be performed blindly. Biopsy of hemangiomas can be performed under direct vision using the laparoscope or with imaging control (see earlier). Extrahepatic biliary obstruction is a relative contraindication, especially if it is long-standing, because

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The combination of sclerotherapy with propranolol has been used to reduce the rebleeding rate related to long-term injection sclerotherapy.[391] Some reported a decrease in the frequency of rebleeding without an increase in complications before obliteration.[392, 393] This combination appeared to be most beneficial in patients with advanced alcoholic liver disease. Others found an increased complication rate (encephalopathy, difficult resuscitation) without reduction of the frequency of rebleeding or its severity.[391]

Surgical Therapy

When patients have bled from varices, surgery is a third therapeutic option. The history of portal decompressive surgery spans 4 decades of the 20th century. In the early 1990s it is not considered a first line of treatment, but in the 1970s therapeutic portacaval anastomosis was the mainstay of therapy. Four randomized trials examined the efficacy of central shunts (end-to-side portacaval anastomosis was done in more than 90% of the patients) in preventing recurrent hemorrhage in patients with cirrhosis (the majority of alcoholic etiology). Control groups received no treatment.

The benefits of shunt surgery over conventional treatment were marginal in a total of 292 patients.[340, 341, 394, 395] Surgical mortality ranged from 7% to 21%, and 5% of patients had a compromised shunt. Survival was slightly increased in the shunt group;[340, 341, 395] it was shortened in a fourth study in 3 of the trials.[394] As expected, the incidence of bleeding was reduced in the surgical group but encephalopathy was increased. When the studies are combined, the survival curve was still slightly better in the surgical group.

The negative experience with postshunt encephalopathy fueled interest in developing new selective decompressive procedures.[329] The distal splenorenal shunt is technically more demanding, requiring an arduous dissection. Complications arise, in part, from an initial learning phase. Seven trials compared this selective shunt to central shunts in the prevention of recurrent hemorrhage. Table 102–6 lists these studies.[396–402] The majority of the patients had alcoholic cirrhosis (78%). Surgical mortality was higher in the distal splenorenal group, reflecting the previously mentioned difficulties; long-term survival was not drastically different. The frequency of postshunt variceal hemorrhage was disturbingly high in some studies, with a high prevalence of shunt occlusion. The prevalence of postshunt encephalopathy, however, was markedly different among the trials. Whereas 3 studies showed a lower rate with distal splenorenal shunting, 3 others did not. The tools used to define encephalopathy varied among studies, but in one report that examined quality of life and hospitalizations for encephalopathy,[398] a clear benefit for the selective procedure was noted.

Patients with nonalcoholic cirrhosis may have a better response to the distal splenorenal shunt,[403] although this was not confirmed by others.[402] The progression of liver disease may result in the development of collaterals from the mesenteric bed and in a loss of selectivity, the original rationale for the operation.[404] Claims for better preservation of liver function after distal splenorenal shunts[405] require further confirmation.

Modifications of the procedure include a pancreaticosplenic venous disconnection[406] to avoid a new pathway for collateralization (Fig. 102–9). The dissection, however, can be particularly difficult in alcoholic patients with chronic pancreatitis. Distal splenorenal shunts are not suitable for patients with tense ascites; transient accumulation of ascitic fluid during volume resuscitation, however, is common and should not preclude the procedure if hepatopetal flow is demonstrated preoperatively. The procedure must be performed by an experienced surgeon; the availability of alternative methods of treatment has reduced the number of shunt procedures worldwide.

Postshunt encephalopathy continues to be a major concern when recommending surgical decompression. No methods predict the development of postsurgical changes in mental state. Transient encephalopathy that occurs around the bleeding episode does not preclude a shunt procedure.[407] Preoperative liver function does not predict the neurologic response to the procedure.[408] Experience with the small-diameter portacaval H graft,[409] in which a preserved portacaval pressure gradient and higher hepatopetal flow result in lower rates of encephalopathy, suggests that a key factor in the incidence of postshunt alteration in mental state is the rate of delivery of neurotoxins from the splanchnic bed to the systemic circulation.[410]

Three studies compared distal splenorenal shunts with sclerotherapy in alcoholic cirrhotic patients (80% to 90% of the study population).[411–413] The rebleeding rate was higher after sclerotherapy, but no differences in survival were seen in all studies. Of patients in the sclerotherapy group, 6% to 31% ultimately underwent shunt surgery. Hepatic portal perfusion was maintained better by sclerotherapy than by selective shunting. One study, comparing end-to-side portacaval anastomosis to sclerotherapy, found surprisingly similar incidences of encephalopathy.[367]

Surgery is proposed for patients considered unresponsive to sclerotherapy.[414] However, sclerotherapy requires a long-term commitment from the patient. The choice of therapy should be based on the assessment of patient's compliance, geographic considerations, and the availability of local expertise.

Future Directions

Transjugular Intrahepatic Portosystemic Shunt Stent

A radiologic technique for the percutaneous placement of an intrahepatic shunt has been developed.[415] The procedure is rapid, requiring 2 to 3 hours to complete, and is performed without anesthesia. It involves localization of the portal vein by ultrasonography and transjugular establishment of a parenchymal tract between a central hepatic and portal vein (Fig. 102–10). An expandable wire mesh stent (diameter 8 to 12 mm)

Table 102–6. RANDOMIZED CONTROLLED TRIALS COMPARING DISTAL SPLENORENAL SHUNTS VERSUS NONSELECTIVE SHUNTS IN PREVENTING RECURRENT VARICEAL HEMORRHAGE*

Trial	Control Shunt	Number of Patients		Alcoholic Cirrhosis (%)	Operative Mortality (%)		Variceal Hemorrhage		Shunt Occlusion (%)		PSE (%)	
		PSS	DSRS		PSS	DSRS	PSS	DSRS	PSS	DSRS	PSS	DSRS
Millikan et al.[396]	RCS, MCS	29	26	72	10	12	31	22	29	14	76	26
Reichle et al.[397]	MCS	14	13	93	7	8	NR†		NR		NR	
Langer et al.[398]	PCA	40	38	82	0	13	5	9	NR		48	36
Grace et al.[399]	PCA	38	43	90	13	9	12	18	15	17	45	51
Harley et al.[400]	PCA	27	26	100	7	12	4	30	NR		32	39
Fischer and McKinley[401]	PSRS	27	29	84	7	10	7	11	12	23	16	8
Spina et al.[402]	PCA	47	46	46	2	2	2	9	NR		17	21
Totals	—	222	221	78	7	9	10	16	20	18	39	30

*PSS = portosystemic shunt; DSRS = distal splenorenal shunt; PSE = portosystemic encephalopathy; RCS = renocaval shunt; MCS = mesocaval shunt; PCA = portacaval anastomosis; PSRS = proximal splenorenal shunt.

†NR = not reported.

Adapted from Grace ND, Conn HO, Resnick RH, et al. Distal splenorenal vs portal-systemic shunts after hemorrhage from varices: a randomized controlled trial. Hepatology 1988; 8:1475–1481.

is placed and a balloon expanded to achieve a reduction of the portal venous pressure gradient to less than 12 mm Hg. A neointimal lining of the stent forms within a few weeks in the dog model.[415]

Experience in nonsurgical candidates with portal hypertension and refractory variceal bleeding[416, 417] showed that TIPS lowered the mean portohepatic pressure gradient with cessation of bleeding. When patients required a greater portosystemic pressure gradient reduction, the stent was further expanded by percutaneous balloon angioplasty.[417] Followup endoscopies within 1 week showed a reduction in size of the varices in all patients. All shunts were patent within the mean followup duration of 5 months, although additional balloon angioplasty procedures were needed for minor strictures in 2 of 8 patients.

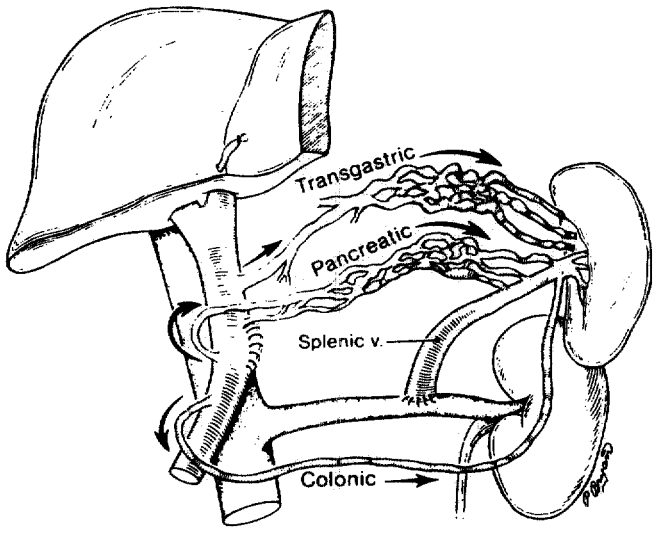


Figure 102–9. Development of new collaterals after distal splenorenal shunt results in loss of selectivity of the operation; transgastric and pancreatic collaterals shunt blood from the portal vein to the splenic venous drainage. (From Warren WD, Millikan WJ, Henderson JM, et al. Splenopancreatic disconnection. Improved selectivity of distal splenorenal shunt. Ann Surg 1986; 204:346–355.)

Further studies are needed to compare present therapeutic modalities with TIPS in terms of rebleeding rate, complication rates, and long-term patency. TIPS was highly effective in controlling both the acute and recurrent hemorrhages in a small uncontrolled prospective study of cirrhotic patients with advanced Child's class and refractory variceal bleeding.[135] Portal pressures were reduced from a mean of 34 to 22 mm Hg, but portal hepatic gradients were not measured. No procedural or intrahepatic complications were reported and hepatic function was preserved. Potential complications, however, include stent migration, hemobilia, and arteriovenous fistula. A major advantage of this procedure is the preservation of the porta hepatis for future transplantation. Results on long-term survival are awaited.

Liver Transplantation

Long-term survival rates with liver transplantation have been reported from some centers to be as high as 70% at 3 years.[418] This approaches the survival seen after elective shunt surgery and allows consideration of recurrent variceal bleeding as an indication for transplantation in patients with decompensated liver disease.[419, 420] However, organ supply and health care costs prohibit its widespread use, and transplantation should be reserved for individuals with variceal hemorrhage and concomitant hepatocellular failure. Still, hemorrhage should be controlled by other means before considering transplantation.

ADDITIONAL BLEEDING SITES

Congestive Gastropathy

Endoscopic descriptions of portal hypertensive gastropathy include a mosaic pattern of 2 to 6 mm erythematous patches separated by a fine yellow or white lattice or, in a more severe form, a granular mucosa with cherry red spots, also termed scarlatiniform pat-

ANGIODYNAMICS, Inc.

Bill To: 603 Queensbury Avenue
Queensbury, NY 12804

Ship To: 543 Queensbury Avenue Suite 4
Queensbury, NY 12804

Phone 518-798-1215
Fax 518-798-3625

FAX TRANSMITTAL

TO: FDA - CDRH

ATTN: DONNA BUCKLEY

CC:

FROM: JEFF MADDISON

SUBJECT: TransJugular Access Set

Number of Pages 2 (Including this cover sheet)

Message:

DONNA,

IF you have any other questions regarding this submission or the Angiotic, give me a call. Brian Kunst will be out of the office today & tomorrow (5/9-5/10)

510(k) Number (if known): K964034

Device Name: Transjugular Access Set

Indications For Use:

The ANGIODYNAMICS, Inc. Transjugular Liver Access Set is intended to be used for transjugular liver access during diagnostic and interventional procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ or Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

ANGIODYNAMICS®

INCORPORATED

April 25, 1997

Donna Buckley
U.S. Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Drive
Rockville, Maryland 20850

Re: Additional Information Request
K964034 - ANGIODYNAMICS® Transjugular Access Set

Dear Ms. Buckley:

The following information is provided in response to your request for additional information regarding the above referenced premarket notification.

The 21 gauge needle is manufactured by Needletech, North Attelboro, Massachussetts. The 14 gauge needle is manufactured by Hawk Medical, Gainesville, Florida.

The following table compares the Access Set described in K964034 to the device described by Hawkins in the article published in the Journal of Vascular and Interventional Radiology.

Device presented in K964034	Device presented in JVIR article Nov. 1994
8 French introducer sheath & hemostasis valve	12 French guiding catheter & hemostasis valve
8 French catheter	8 French catheter
5 French AngiOptic Catheter	5 French catheter
14 gauge curved needle with "extra blunt" tip	14 gauge curved needle with blunt tip
21 gauge beveled tip needle	22 gauge beveled tip needle

8 French introducer sheath vs. 12 French guiding catheter:

The 8 French introducer sheath presented in K964034 and the 12 French guiding catheter presented in the JVIR article are the same device. The 8F refers to the ID or the maximum diameter of the catheter that can be introduced through the sheath. The OD is 12F. Since industry standard for introducers is to label them with the ID or the maximum size of the device it is intended to introduce, it will be referred to as an 8F introducer sheath.

8 French PTFE catheter vs. 8 French catheter:

The 8 French PTFE catheter presented in K964034 and the 8 French catheter presented in the JVIR article are the same device.

603 Queensbury Ave. • Queensbury, NY 12804 USA • 518-798-1215 • 800-77ANGIO • fax 518-798-3625
E-mail: http://www.angiodynamics.com

5 French AngiOptic catheter vs. 5 French catheter.

The 5 French catheter used in device described in the JVIR article was constructed from a Teflon shaft, while the device presented in K964034 uses a commercially available nylon shaft straight AngiOptic catheter (K954423). The reason for this change was that the straight AngiOptic is already in our product line and the purpose of the 5F catheter is for contrast injection – consistent with the design goal of the AngiOptic. There are no dimensional differences between the two devices.

14 gauge curved needle with "extra-blunt" tip vs. 14 gauge curved needle with blunt tip:

As figure 1 indicates the change from the blunt tip to the "extra-blunt" tip was to reduce the possibility of severing the tip of the 5 French catheter while retracting it through the 14 gauge curved needle.

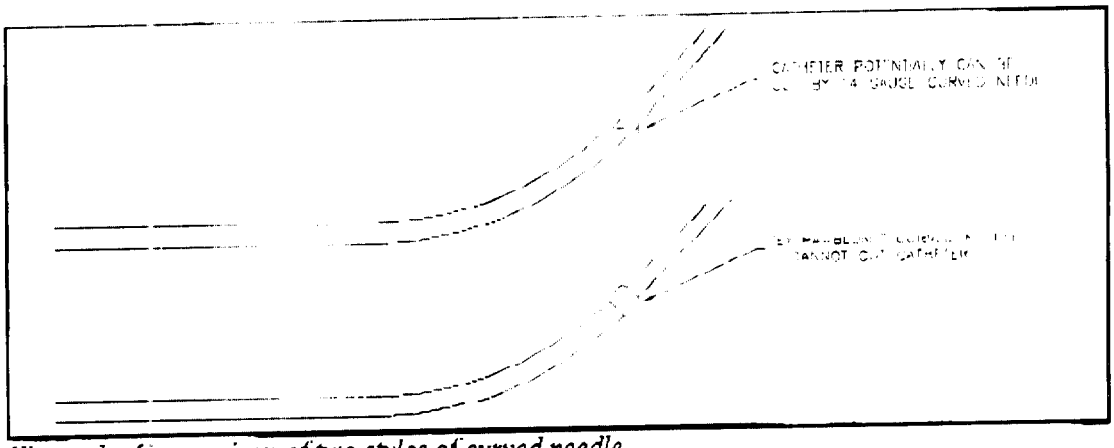


Figure 1 - Comparison of two styles of curved needle

21 gauge needle vs. 22 gauge needle:

The reason for increasing the size of the beveled point needle from 22 gauge to 21 gauge was to allow the use of an .018" guidewire instead of an .016" guidewire. A .018" can in some instances be easier to track through the vasculature and gives the physician more flexibility.

The differences between the device proposed in the 510(k) and the device described in the article are very slight and would not affect the product's safe and effective use.

If there are any further questions regarding this application, please feel free to contact me at 518-798-1215 extension 123.

Sincerely,
ANGIODYNAMICS, Inc

Brian Kunst
Director, Regulatory Affairs and Quality Assurance

ANGIODYNAMICS, Inc.
603 Queensbury Avenue, Queensbury, New York 12804
Phone: 518-798-1215 Fax: 518-798-3625

FAX

Date: April 21, 1997
Number of pages including cover sheet: 6

To:
Donna Buckley
Division of Cardiovascular Device

Phone:
Fax phone: 301-480-4204
CC:

From:
Brian S. Kunst
Director, Regulatory Affairs and Quality Assurance

Phone: 518-798-1215, ext. 123
Fax: 518-798-3625

REMARKS: ☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please comment

Re: K964034 Additional Information

Dear Ms. Buckley,

Attached is a copy of an article entitled Fine Needle Transjugular Portal Venous Access System by Irvin Hawkins, MD. Dr. Hawkins specified the features of the AngioDynamics Transjugular Access Set described in K964034, based on his clinical experience as described in this paper. This paper provides confidence that the AngioDynamics Transjugular Access Set will be clinically acceptable for its intended use.

If you have any questions, please call me at 518-798-1215, extension 123.

Sincerely,

ANGIODYNAMICS®, Inc.

Brian Kunst
Director of Regulatory Affairs/Quality Assurance

Fine-Needle Transjugular Portal Venous Access System[1]

Scott R. Kerns, MD
Frank W. Sabatelli, MD[2]
Irvin F. Hawkins, Jr, MD

THE transjugular intrahepatic portosystemic shunt (TIPS) has become a viable option in the treatment of patients with portal hypertension. Numerous series have shown it effectively lowers portal pressures, thereby reducing the chance of variceal hemorrhage and allowing resorption of ascites (1–4). These results are achieved with a lower procedural morbidity and mortality compared with those associated with surgical shunting. Excluding hepatic encephalopathy and late shunt stenosis or occlusion, the complication rate of TIPS procedures has been reported to be less than 10% (5). Although rare, serious and potentially fatal complications may occur including hepatic artery occlusion or pseudoaneurysm formation, arterioportal or arteriovenous fistula formation, hemobilia, and intraperitoneal hemorrhage. Various techniques and equipment for transjugular portal venous access have been proposed in part to decrease procedural complications while maintaining a high technical success rate (1,6,7). With these goals in mind we have developed and clinically tested a modified transjugular portal venous access system, and in this report describe our experience using it to perform TIPS procedures in 75 patients.

Index terms: Catheters and catheterization, technology, 957.123 • Portal vein, 957.123 • Shunts, portosystemic, 959.153

JVIR 1994; 5:835–837

[1] From the Department of Radiology, Shands Teaching Hospital and Clinics, University of Florida, 1600 SW Archer Rd, Gainesville, FL 32610. From the 1994 SCVIR annual meeting. Received March 22, 1994; revision requested June 1; revision received June 20; accepted June 24. Address reprint requests to S.R.K.
[2] Current address: CPO Radiology Associates, Plano, Tex.

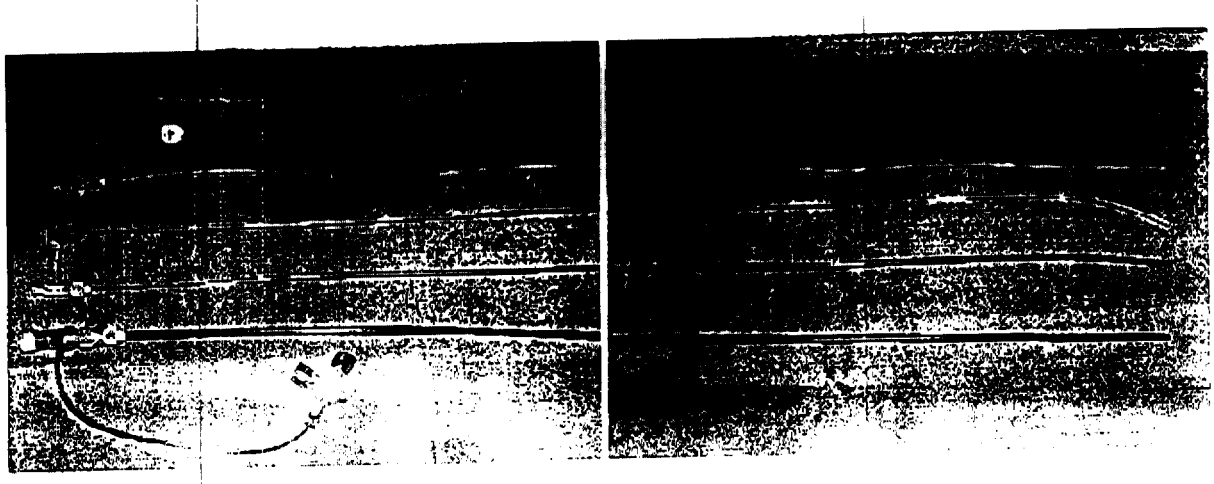
PATIENTS AND METHODS

The fine-needle set is a coaxial system consisting primarily of five components (AngioDynamics, Glens Falls, NY) (Figs 1, 2). The inner component consists of an 82-cm-long, 22-gauge, thin-wall puncture needle inside a 70-cm-long, 5-F catheter. A 0.016-inch nitinol guide wire with a highly radiopaque tip (Microvena, White Bear Lake, Minn) is placed into the needle. When the needle is withdrawn into the 5-F catheter, a stop on the shaft of the needle exactly aligns their tips. This prevents accidental advancement of the needle through the wall of the catheter.

The outer component consists of a blunt-tip, 60-cm-long, 14-gauge metal cannula inside a 57-cm-long, 6-F catheter. The cannula has a 30° curve over its distal 4 cm that directs the course of the smaller puncture needle. A metal handle on the hub of the cannula indicates the direction of its curved tip and acts as a handle for torquing the cannula. The entire assembly is placed through a 44-cm-long, 12-F, thick-walled Teflon guiding catheter with a hemostasis valve and side port.

This fine-needle system was used to perform TIPS in 75 patients between May 1991 and March 1994. The most common presentation was recurrent variceal hemorrhage refractory to sclerotherapy. After the procedure, patients were observed at least overnight with daily serial measurements of hematocrit levels. A color Doppler flow imaging examination was performed the morning after the procedure to confirm shunt patency and to evaluate for vessel occlusion or pseudoaneurysm, biliary obstruction, or any change in the amount or character of ascites.

The general TIPS technique has been previously described (1–3); however, several modifications were used. The right internal jugular vein was entered under direct ultrasound (US) guidance with a 21-gauge needle. Once in the hepatic vein, the 12-F guiding catheter was retracted and the curved metal cannula rotated toward the expected location of the right portal vein. The 22-gauge needle was advanced in 1–2-mm increments, and the area was tested by gently probing with the preloaded 0.016-inch guide wire or injecting contrast material via a Tuohy-Borst adapter. This was continued until the portal vein was entered, an errant puncture of another structure occurred, or the needle had been advanced 5 or 6 cm. Errant punctures included puncture of the hepatic artery, bile duct, or liver capsule. If an errant puncture occurred or the needle advanced 5 or 6 cm without entering the portal vein, the needle was retracted, the cannula redirected, and a new series of passes performed.



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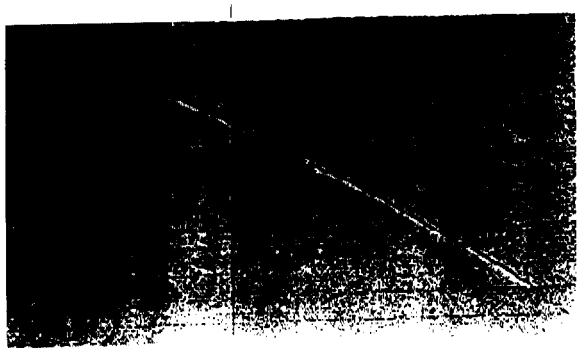

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Figures 1, 2. (1) Disassembled fine-needle transjugular portal venous access system. From top to bottom: 22-gauge needle with stop on proximal shaft, 5-F catheter, 14-gauge blunt metal cannula, 8-F catheter, and 12-F guiding catheter with hemostasis valve and side port. (2) Assembled fine-needle portal venous access system.

Once the 22-gauge needle had entered the portal venous system without traversing the hepatic artery or biliary system, the 0.016-inch guide wire was advanced followed by the needle and 5-F catheter. Portography was performed to confirm that the right portal vein had been entered. The 8-F and 12-F catheters were then advanced into the portal vein over a guide wire followed by balloon dilation and placement of a Wallstent (Schneider, Minneapolis, Minn). The sturdy 12-F catheter provided direct access to the main portal vein for balloon expansion and stent placement without buckling or resistance.

RESULTS

We were able to place a functioning shunt in 72 of 75 patients, for a technical success rate of 96%. Among our failures, one patient had previous portal vein thrombosis with partial recanalization on imaging studies. In this patient, we were unable to enter a recanalized branch despite approximately 50 passes. In another patient the posterior branch of the right portal vein thrombosed along with the shunt after dilation of the shunt. The patient returned later for successful placement of a shunt to the left portal vein. The third failure occurred in a patient with a large liver and very small portal vein branches. We were unable to enter the portal venous system, and he later underwent successful creation of a distal splenorenal shunt.

We had no difficulty advancing the 0.016-inch guide wire into the portal system, and it never was sheared off by the sharp needle. However, we did not attempt to pass the needle around acute turns for fear of this occurring.

No patients developed clinical signs of hemorrhage or a drop in hematocrit, and no evidence of vascular injury, biliary obstruction, or hemoperitoneum was seen on the postprocedure US examinations. The hepatic artery, biliary system, and liver capsule were inadvertently punctured in approximately 5%, 10%, and 20% of patients, respectively. No errant puncture of the gallbladder, colon, or right kidney occurred. In two patients (3%) the main portal vein, which is believed to be extrahepatic, was entered without sequelae. In all of these patients new passes were performed to complete the TIPS without violating adjacent structures.

We found that in patients with small livers, the portal bifurcation was frequently almost directly anterior to the hepatic vein, which necessitated a sharp turn anterior to make a successful puncture. In these cases, the angle of the blunt cannula can be increased by carefully bending it by hand to the desired amount. Also, the 22-gauge needle may be bent as well, although this should be done with the 0.016 inch guide wire inside it to avoid compromising the needle lumen. The curve of the bent 22-gauge needle naturally follows and extends the curve of the metal cannula.

DISCUSSION

In general, TIPS is considered a relatively safe means of portal decompression in patients with portal hypertension. Although most procedural complications either are treated conservatively or have no significant impact on the patient's care, serious and potentially fatal complications can and do occur (5,8–10). To improve the safety of this procedure, thereby potentially increasing its clinical usefulness, we have attempted to refine what may be the most difficult and dangerous part of this procedure—the transjugular portal venous access.

The fine-needle access system described is a modification of other currently available systems used for TIPS (1,11,12). Unlike the system described Rösch et al (12), we used a small-gauge hollow needle instead of a trocar to make passes toward the portal vein. Passes are short, and the location of the needle tip is checked before proceeding further. This enables one to avoid traversing or transecting other vital structures in the vicinity of the portal vein. Most investigators report using a larger gauge sharp Colapinto needle or the Rösch set with its trocar stylet to perform the puncture. Thrusts are made toward the portal vein, and aspiration is applied while the needle or catheter is withdrawn until blood return is obtained. Potentially, a vital structure could be entered on the way to the portal vein without the operator knowing it. In approximately one-half of patients another vital structure lies in the path between the right hepatic vein and the portal bifurcation (13). This may result in arterial injury, fistula formation, or communication of the shunt with the biliary tree. In addition to procedural morbidity, the latter should probably be avoided since preliminary data show this may incite pseudointimal hyperplasia leading to shunt failure (14). With this system the tract is tested before the sheath is advanced and the shunt is placed, thereby avoiding these problems.

The guiding catheter, which is longer and has a thicker wall than the thin-walled sheath provided with the Rösch set, provides access to the portal vein in all patients without buckling into the right atrium. We and others have found that with the Rösch set this has not always been the case (15). Its length allows it to be placed into the portal vein completely eliminating any resistance in the parenchymal tract to the balloon catheter or Wallstent deployment device.

In conclusion, we believe this fine-needle transjugular portal venous access system can be used safely and effectively for the TIPS placement. This system enhances the ability to avoid intervening vital structures and potentially lessen the effect of errant punctures, overcome parenchymal tract resistance in extremely cirrhotic livers, and prevent buckling into the right atrium. Ultimately, the choice of access system will depend on how much significance the operator places on these factors.

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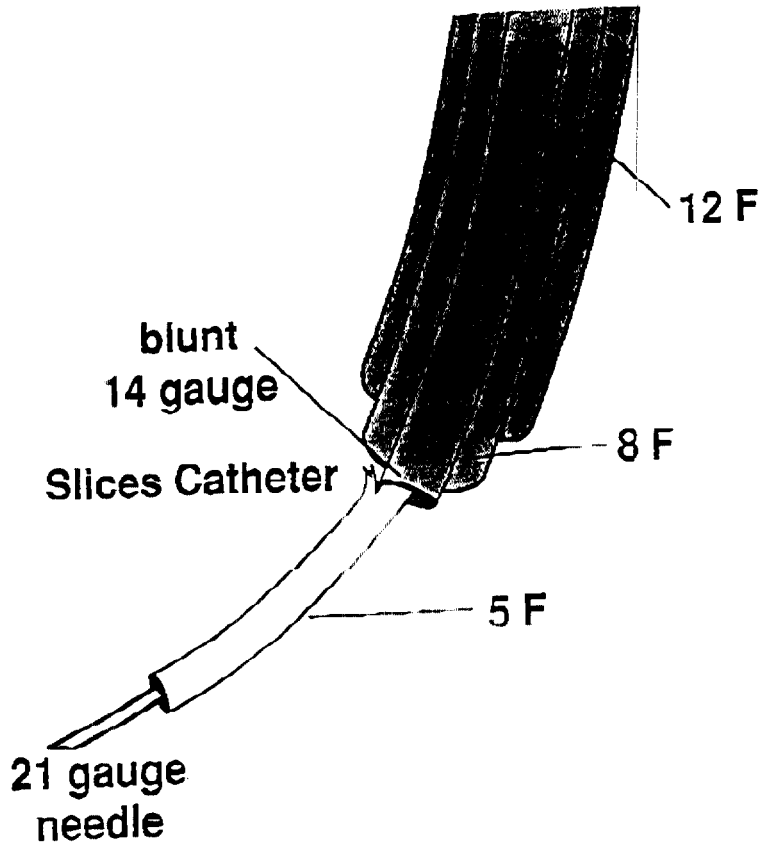
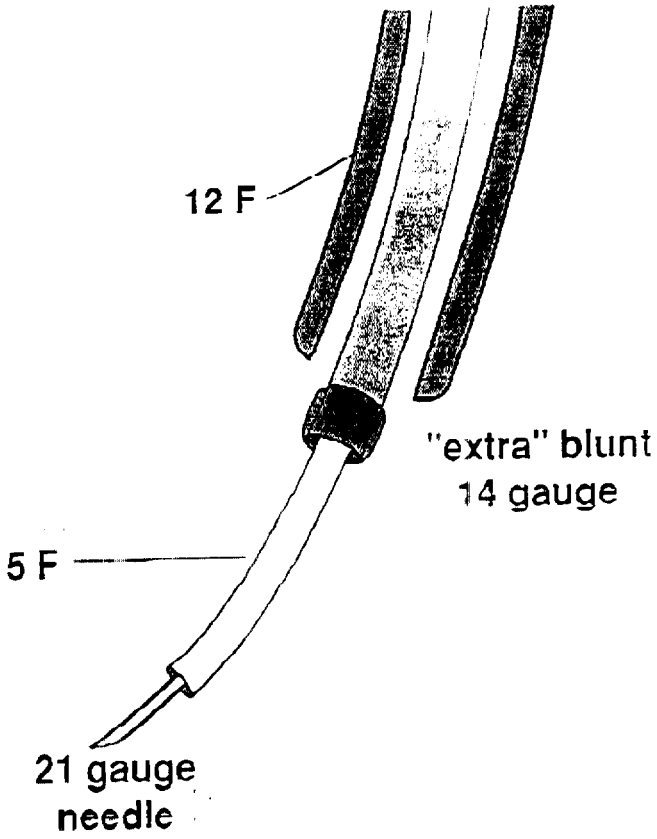


Previous fine needle system. Thin-walled, "blunt" 14-gauge Ross needle "slices" 5 French catheter during retraction.



New "extra blunt" Ross needle has a rounded tip which will not cut inner 5 French catheter. The coaxial 8 French catheter has been eliminated. Note: The 21-gauge needle is advanced during search for portal vein. The 5 French catheter traverses liver only after 21-gauge needle enters portal vein.

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 05, 1997

ANGIODYNAMICS, INC.
603 QUEENSBURY AVE.
QUEENSBURY, NY 12804
ATTN: BRIAN KUNST

510(k) Number: K964034
Product: TRANSJUGULAR
ACCESS SET

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

February 4, 1997

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Drive
Rockville, Maryland 20850

Re: Additional Information request
K964034 - ANGIODYNAMICS®
Transjugular Access Set

Dear Document Control Staff:

The following information is provided in response to your request for additional information, dated January 6, 1997, regarding the above referenced premarket notification.

1). Indications For Use

ANGIODYNAMICS, Inc. wishes to revise the indication for use for the Transjugular Access Set. The revised indication for use is as follows:

" Transjugular liver access in diagnostic and interventional procedures"

This is identical to the labeled indication for use of the predicate device. Attachment 1 contains the revised instructions for use.

2). Beveled Needle

The purpose for using a hollow needle in the ANGIODYNAMICS® Transjugular Access Set instead of the solid pencil point needle used in the Cook® Rosch-Uchida Transjugular Liver Access Set is to enable contrast injections through the hollow needle during the procedure to assure proper device placement. The Transjugular Access Set was developed in cooperation with Dr. Irvin Hawkins, Professor of Radiology and Chief of Interventional Radiology at Shands Teaching Hospital, Gainesville, FL, whose clinical experience guided the design of this feature. Note that the O.D. of the pencil point needle is 20ga (.035"), which is equivalent to the ANGIODYNAMICS, Inc. needle 21ga (.032").

Both the ANGIODYNAMICS, Inc. Transjugular Access Set and the Cook® Rosch-Uchida Transjugular Liver Access Set contain a curved component used for directing the catheter. Both are 14ga in diameter and are made of stainless steel. ANGIODYNAMICS, Inc. refers to the shape of the needle as a Ross needle, while Cook® refers to theirs as a stiffening cannula. There are no functional differences.

3). Package Label

Originally, the needle that was intended to be used in the Transjugular Access Set was a 22g thin walled needle (.0280 O.D. x .0205 I.D.). A slight variation was made to this by changing the 22g thin walled needle to a 21g thin walled needle (.032" O.D. x .024" I.D.). The purpose of this change was to enable the use of an .018" guidewire, since the 22g needle limited guidewire size to .016". A revised package label is included as Attachment 2.

If there are any further questions regarding this application, please feel free to contact me at 518-798-1215 extension 190.

Sincerely,
ANGIODYNAMICS, Inc.

Jeffrey R. Mannion
Regulatory Affairs Associate

Attachment 1

(b) (4) Instructions For Use Draft

(b) (4) Instructions For Use Draft

(b) (4) Instructions For Use Draft

(b) (4) Instructions For Use Draft

Attachment 2

(b) (4) Instructions For Use Draft

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 1997

Mr. Jeffrey R. Mannion
Regulatory Affairs Associate
Angiodynamics, Incorporated
603 Queensbury Avenue
Queensbury, New York 12804

Re: K964034
Transjugular Access Set
Dated: September 30, 1996
Received: October 8, 1996

Dear Mr. Mannion:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

1. Please address the following issues regarding the indications for use:

   a. Each indication for use needs to be specified and supported. You indicate in Section 5 that your device is "intended to be used for transjugular access in diagnostic and interventional procedures, such as biliary drainage, liver access and biopsy, placement of vena cava filters, and cholangiography." However, the device to which you claim substantial equivalence is indicated only for liver access. Therefore, please address the following: (1) revise the indication for your device to specify the areas where it is to be used; (2) identify a predicate device for each indication; and (3) demonstrate that your device is substantially equivalent to the predicate by providing comparative data and performance data.

   b. Please list the vena cava filters that you intend to place with your device and provide either an explanation or testing to demonstrate the adequacy of your device to place these filters without incident.

2. The predicate device includes a pencil point needle, whereas your device includes a Ross needle and a beveled tip needle. Please provide either the trade names and manufacturers of devices that use the 14 gauge curved Ross needle and the 21 gauge beveled tip needle for the same indications or provide an article from a peer reviewed journal that indicates that these needle tips and gauges are adequate for the stated indications.

3. The package label indicates that the kit includes a 22 gauge beveled point needle, whereas the rest of the file references a 21 gauge beveled point needle. Please clarify this discrepancy.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have questions concerning the contents of this letter, please contact Donna Buckley at (301) 443-8243. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

Tara A. Ryan for

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Mr. Jeffrey R. Mannion
Regulatory Affairs Associate
Angiodynamics, Incorporated
603 Queensbury Avenue
Queensbury, New York 12804

Re: K964034
Transjugular Access Set
Dated: September 30, 1996
Received: October 8, 1996

Dear Mr. Mannion:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

1. Please address the following issues regarding the indications for use:

   a. Each indication for use needs to be specified and supported. You indicate in Section 5 that your device is "intended to be used for transjugular access in diagnostic and interventional procedures, such as biliary drainage, liver access and biopsy, placement of vena cava filters, and cholangiography." However, the device to which you claim substantial equivalence is indicated only for liver access. Therefore, please address the following: (1) revise the indication for your device to specify the areas where it is to be used; (2) identify a predicate device for each indication; and (3) demonstrate that your device is substantially equivalent to the predicate by providing comparative data and performance data.

   b. Please list the vena cava filters that you intend to place with your device and provide either an explanation or testing to demonstrate the adequacy of your device to place these filters without incident.

2. The predicate device includes a pencil point needle, whereas your device includes a Ross needle and a beveled tip needle. Please provide either the trade names and manufacturers of devices that use the 14 gauge curved Ross needle and the 21 gauge beveled tip needle for the same indications or provide an article from a peer reviewed journal that indicates that these needle tips and gauges are adequate for the stated indications.

3. The package label indicates that the kit includes a 22 gauge beveled point needle, whereas the rest of the file references a 21 gauge beveled point needle. Please clarify this discrepancy.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

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Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Prepared by:DBUCKLEY:swf:1/2/97
final:swf:1/6/97
cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.O.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
450	Buckley	1/6/97						
450	JHannecken	1/6/97						
450	Rep	1/6/97						

U.S. GPO 1986-169-089

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Donna Buckley

Subject: 510(k) Number K964034

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Is substantially equivalent to marketed devices.
- ☐ Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☒ Requires more data.
- ☐ Accepted for review _____ (date)
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☒NO
Is this device subject to the Tracking Regulation?	☐YES	☒NO
Was clinical data necessary to support the review of this 510(k)?	☐YES	☒NO
Is this a prescription device?	☒YES	☐NO
Was this 510(k) reviewed by a Third Party?	☐YES	☒NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☒Enclosed
(required for originals received 3-14-95 and after)

☐A 510(k) summary OR ☒A 510(k) statement

☐ The required certification and summary for class III devices N/A

☒ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☒ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

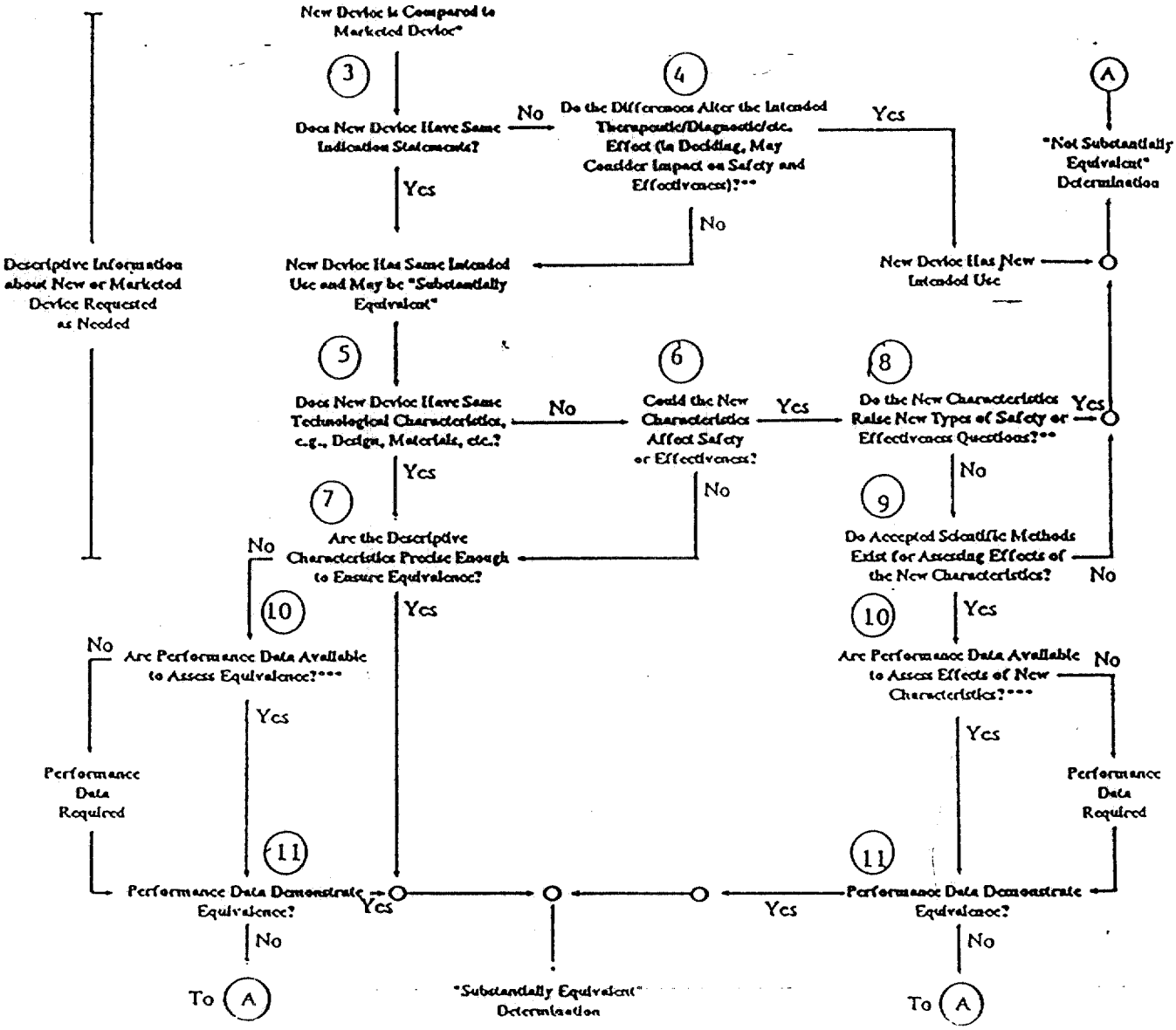
_____ _____

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Revised:7-1-96

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

DATE: January 2, 1997

TO: File K964034

FROM: Donna C. Buckley
Mechanical Engineer, FDA/CDRH/ODE/DCRND/ICDG

SUBJECT: 510(k) Review of Transjugular Access Kit (catheter introducer) -- Angiodynamics

CONTACT: Brian Kunst -- (518) 798-1215 ext.190; FAX (518) 798-3625

DECISION: ADDITIONAL INFORMATION REQUIRED

INTENDED USE: The Transjugular Access Set is intended to be used for percutaneous transjugular access during diagnostic and/or therapeutic interventional procedures. The examples of procedures provided were biliary drainage, liver access and biopsy, placement of vena cava filters, and cholangiography. I spoke with Brenda Bolden (DDIG) and Richard Felton (DGRD) with regard to the device design and the indications for use. Both claimed that the indications for use need clarification and justification prior to a detailed review of the device design and testing. For example, there are no known predicate intravascular liver biopsy devices.

DESCRIPTION: The access kit is comprised of the following components and corresponding 510(k) numbers are noted where applicable:
1) 8F introducer sheath
2) hemostasis valve (K894446)
3) 8F PTFE catheter
4) 5F AngioOptic catheter (similar to K954423)
5) 14 guage curved Ross needle
6) 21 guage beveled tip needle
7) 1 cc syringe (K905447)
8) 10 cc syringe (K905447)
9) y-adapter (K905447)
10) dual check valve (K905447)

PREDICATE INFORMATION: The predicate device is Cook's Transjugular Liver Access Set. A letter was provided from Cook that stated that the device is a currently marketed modified preamendment device.

BENCH TESTING: Pull testing was performed on the 8F catheter, the 8F catheter introducer and the 5F AngioOptic angiographic catheter. Test results appear adequate.

BIOCOMPATIBILITY: Biocompatibility test information was provided for the following: (1) hemolysis; (2) cytotoxicity; (3) pyrogenicity; (4) irritation and (5) implantation. A systemic toxicity study was also performed with mice. Test results appear adequate.

STERILIZATION/PACKAGING:

EtO sterilization will be performed in accordance with AAMI Guidelines for Industrial Ethylene Oxide Sterilization of Medical Devices (SAL > 10^{-6}, ethylene oxide and ethylene chlorohydrin residuals < 25 ppm, ethylene glycol residuals < 250 ppm). Pyrogen testing will also be performed in accordance with the United States Pharmacopia Bacterial Endotoxins Test. The access set is packaged in Tyvek to polyethylene/polyester Mylar pouches. All packaging materials are identical to those used to package the AngioOptic angiographic catheters (K954423).

DOCUMENTATION:

Indications for Use	X			
Truthful and Accurate Statement	X			
Safety and Effectiveness	X	Statement	___	Summary

CORRESPONDENCE:

Cook Regulatory Affairs -- April Lavender
Ms. Lavander reported that their transjugular access kit is a modified preamendment device. Registration number: A176504.

ADDITIONAL INFORMATION REQUESTED:

1. Please address the following issues regarding the indications for use:

   a. Each indication for use needs to be specified and supported. You indicate in Section 5 that your device is "intended to be used for transjugular access in diagnostic and interventional procedures, such as biliary drainage, liver access and biopsy, placement of vena cava filters, and cholangiography." (b) (4) [redacted]

   b. (b) (4) [redacted]

   c. (b) (4) [redacted]

(b) (4)

2. (b) (4)

3. (b) (4)

RECOMMENDATION:

I recommend that the above additional information is required. Several issues need to be addressed prior to a substantially equivalent determination.

1. The preamendment status of the predicate should be established.
2. A 510(k) kit certification should be obtained.
3. The indications for use should be clearly stated.
4. Depending on the indications, either consult requests or separate 510(k)s should be submitted to DRAERD and/or DDIG.
5. Testing should be evaluated for each indication.

Donna Buckley

Concur
1/6/97

DCRND Screening Checklist for Premarket Notification 510(k)

Device: Transjugular Access Set	K964034
Submitter: Rhythmodynamics	

Items which should be Included *(circle missing & needed information)*	✓ Yes	✓ No	✓ if Item Needed & MISSING
1. General information: a) trade name, b) common name, c) establishment registration #, d) address of manufacturer, e) device class, f) new or modification, g) predicate device identified, h) 513/514 compliance (none yet available), i) Truth and Accuracy Statement, j) Indications for Use Statement (separate page)	✓		
2. SMDA requirements: 510(k) summary or statement (any Class device)	✓		
Class III Certification & Summary (if Class III)	N/A		
3. Proposed Labeling: a) package labels, b) statement of intended use, c) advertisements or promotional materials, d) MRI compatibility (if claimed)	✓		
4. Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals	✓		
5. Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: a) labeling, b) intended use, c) physical characteristics, d) anatomical sites, f) performance (bench, animal, clinical) testing, g) safety characteristics	✓		
6. Biocompatibility data for all patient-contacting materials, OR, certification of identical material/formulation: a) component & material, b) identify patient-contacting materials, c) biocompatibility of final sterilized product	✓		
7. Sterilization and expiration dating information: a) sterilization method, b) SAL, c) packaging, d) specify pyrogen free, e) ETO residues, f) radiation dose	✓		
8. Software validation & verification: a) hazard analysis, b) level of concern, c) development documentation, d) certification	N/A		
9. Meets current DCRND guidelines and applicable standards for this device: a) specify guidance, b) comply with content	✓		

Items shaded under "No" are necessary for all submissions. Circled items and items with checks in the "Needed & MISSING" column must be submitted before acceptance of the document.

Pass Screening: ✓ Yes ____ No Reviewer: Teresa Swallwood Date: 10/11/96

For DCRND Use Only

DCRND Classification Checklist for Premarket Notification 510(k)

Device: Transpyloric Access Set	K964034
Submitter: Angiodynamics	
Date received: Original 510(k): 8-OCT-96 This submission: 8-OCT-96	Review cycle 1

Review Tier (circle one): I, II, III

(for Tier I, complete items 1-5 on the Screening Checklist)

Question	Yes	No
A. Is the product a device?	X	
B. Is the device exempt from 510(k) by regulation or policy?		X
C. Expedited Review Status: Requested by sponsor		X
Identified by DCRND		X
Granted by DCRND		
D. Has this device has been the subject of a previous NSE decision?		
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E. Has the sponsor been the subject of an integrity investigation?		
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Administrative Reviewer Signature: Teresa Smallwood Date: 10/11/96

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 08, 1996

ANGIODYNAMICS
603 QUEENSBURY AVE.
QUEENSBURY, NY 12804
ATTN: BRIAN KUNST

510(k) Number: K964034
Received: 08-OCT-96
Product: TRANSJUGULAR ACCESS SET

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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522 (a) (1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance at the number below for more information.

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. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

If you have procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or call me at (301) 594-1190.

Sincerely yours,

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

K964034

ANGIODYNAMICS®

INCORPORATED

September 30, 1996

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Drive
Rockville, Maryland 20850

Re: 510(k) Notification for
Transjugular Access Set

Dear Document Control Staff:

Pursuant to the requirements of Section 510(k) of the Food, Drug and Cosmetic Act, notification is made of the intention of ANGIODYNAMICS®, Inc. to manufacture and market the following:

Transjugular Access Set

We consider our intent to market this device as confidential commercial information and request that it be considered as such by FDA. We have not disclosed our intent to market this device to anyone except employees of our establishment and have taken precautions to protect this confidentiality.

Thank you in advance for your consideration of this application. If there are any questions, please feel free to contact Brian Kunst, Director of RA/QA, at 518-798-1215, extension 123.

RECEIVED
OCT 10 10 40
FDA/ODE/DMS

Sincerely,
ANGIODYNAMICS, Inc.

Jeffrey R. Mannion
Regulatory Affairs Associate

603 Queensbury Ave. • Queensbury, NY 12804 USA • 518-798-1215 • 800-77ANGIO • fax: 518-798-3625

SN
CV
2

510(k) Number (if known): _____

Device Name: Transjugular Access Set

Indications For Use: The AngioDynamics Transjugular Access Set is intended to be used for percutaneous transjugular access during diagnostic and/or therapeutic interventional procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K964034

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Premarket Notification
Transjugular Access Set

TABLE OF CONTENTS

Premarket Notification
Transjugular Access Set

Truthful And Accurate Statement:
[As required by 21 CFR 807.87(j)]

I certify that in my capacity as Regulatory Affairs Associate at ANGIODYNAMICS®, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Jeffrey R. Mannion
(Typed Name)

9/30/96
(Date)

K964034
(Premarket Notification (510(k) Number)

Premarket Notification
Transjugular Access Set

General Information:

ANGIODYNAMICS, Inc intends to introduce the following device into commercial distribution:

a)	**Trade Name:**	Transjugular Access Set
b)	**Device Name:**	Catheter Introducer
c)	**Established Registration Number**	3019211
d)	**Manufacturing Site Address:**	ANGIODYNAMICS® 603 Queensbury Avenue Queensbury, New York 12804
e)	**Sterilization Site Address:**	Cosmed II, Inc. 8 Industrial Drive Coventry, Rhode Island 02816
f)	**Sterilizer Establishment Registration Number**	1222273
e)	**Classification:**	870.1340 Catheter Introducer Product Code: 74DYB Class II Cardiovascular Devices

f) **Device Equivalence:**

This product is substantially equivalent to the following devices:

- Cook® Rosch-Uchida Transjugular Liver Access Set

This device does not present additional risks to patients or different considerations regarding safety and effectiveness than those presented by the pre-Amendment devices.

g) **Performance Standards:** None Established

h) **ANGIODYNAMICS® Contact Information:**

Name	Brian Kunst, Director of RA/QA
Address:	603 Queensbury Avenue Queensbury, New York 12804
Phone	(518) 798-1215 extension 123
Fax:	(518) 798-3625

Premarket Notification
Transjugular Access Set

Summary And Certification:

I certify that in my capacity as Regulatory Affairs Associate at ANGIODYNAMICS®, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers and trade secrets and confidential commercial information as defined in 21 CFR 20.61.

Jeffrey R. Mannion
Regulatory Affairs Associate

Premarket Notification
Transjugular Access Set

Proposed Labeling

Instructions for Use

PROPOSED ACCESS TECHNIQUE

8. Advance the 21 gauge beveled tip needle into the suspected location of the target site.

9. Again, inject contrast to determine the exact locations of the 21 gauge needle and the target site.

10. When the correct location is verified, unlock the hubs of the 5 French catheter and the 21 gauge beveled needle, and advance the 5 French catheter through the 14 gauge Ross needle into the target site.

11. Once in the target site, the torque wire and 21 gauge beveled needle can be removed, and replaced with an .035" Amplatz superstiff guidewire.

12. Inject additional contrast to ensure proper catheter and wire location.

13. Once in the target site, the 5 French catheter and 14 gauge Ross needle can be removed, being sure not to remove the Amplatz wire. Then the proper device, depending on the procedure, can be placed into the target site (i.e. biliary drainage catheter, balloon catheter, biopsy needle.)

ANGIODYNAMICS®
INCORPORATED

603 Queensbury Ave., Queensbury, N.Y. 12804 U.S.A.
Tel. 518-798-1215 FAX 518-798-3625

IC114 Rev. A 9/96

TRANSJUGULAR ACCESS SET

INSTRUCTIONS FOR USE

ANGIODYNAMICS®
INCORPORATED

SET ASSEMBLY

Figure 1 illustrates the proper set assembly.

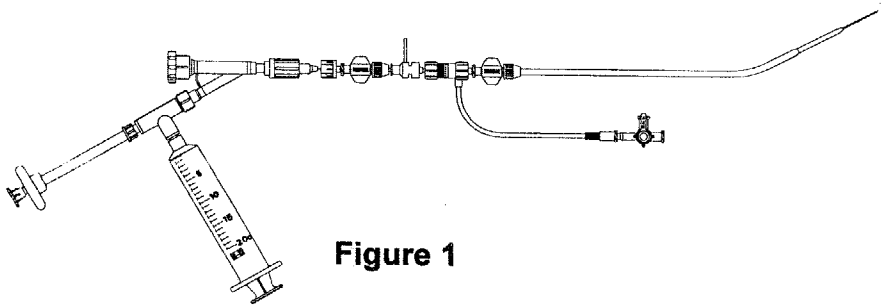


Figure 1

PROPOSED ACCESS TECHNIQUE

NOTE: The exact technique to gain access to the desired section of the vasculature is at the discretion of the physician. One proposed access technique is outlined below:

1. Prior to the procedure, Doppler ultrasound is used to evaluate target site patency.

2. Percutaneously access the right internal jugular vein.

3. Place the 8 French Introducer into a position within the vasculature proximal to the target site using the 8 French catheter as a dilator (Figure 2).

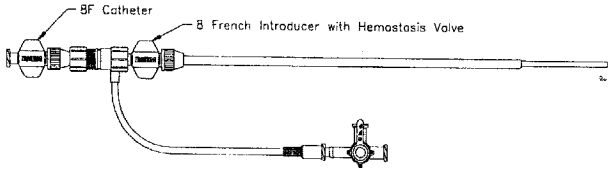


Figure 2

INDICATION FOR USE

- Percutaneous transjugular access to perform an interventional diagnostic and/or therapeutic procedure.

- The Access Set is supplied sterile and is intended for one time use only. Do not re-sterilize.

CAUTIONS

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

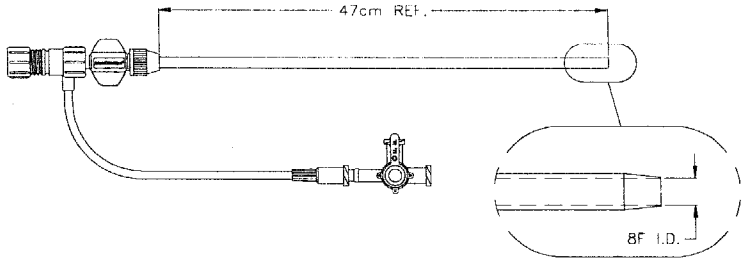
- Store in a cool, dry place. Protect from UV light.

- Prior to use, assemble and disassemble the set using aseptic techniques. Tighten all Luer lock fittings by hand on the furnished catheters prior to using.

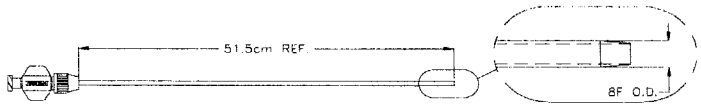
WARNINGS

- Transjugular access should be performed by a physician familiar with the technique, complications, and contraindications.

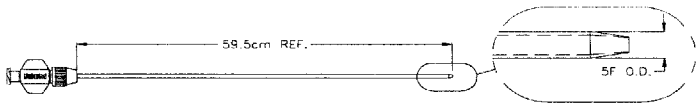
COMPONENTS



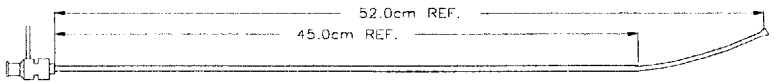
8 French Introducer with Hemostasis Valve and Sidearm



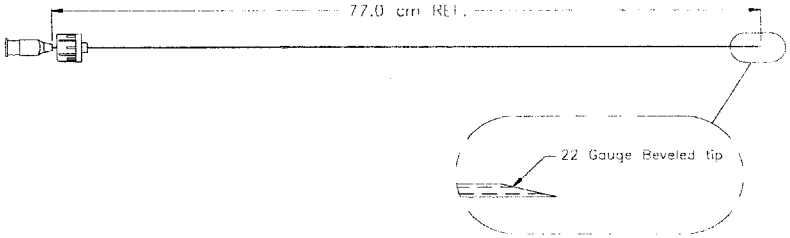
8 French PTFE Catheter



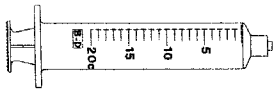
5 French AngiOptic Catheter



14 Gauge Ross Needle

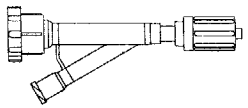


21 Gauge Needle

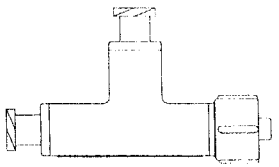


20cc Luer Lock Syringe

1cc Luer Lock Syringe



Hemostasis Y-valve



Dual Check Valve

TABLE OF CONTENTS

Read these "INSTRUCTIONS FOR USE" thoroughly before using the Transjugular Access Set.

The physician should review all references to become familiar with the product applications prior to use.

PROPOSED ACCESS TECHNIQUE

4. Remove the 8 French catheter and inject contrast through the sidearm of the hemostasis valve on the 8 French Introducer to determine the exact location of the target site.

5. Assemble the puncture complex (21 gauge beveled tip needle, 5 French coaxial catheter Luer locked to the 21 gauge needle, and outer 14 gauge blunt tip Ross needle, .018" torque wire (Figure 3).

Figure 3

6. Advance the puncture complex through the 8 French Introducer and attach the fluid management components (Figure 4).

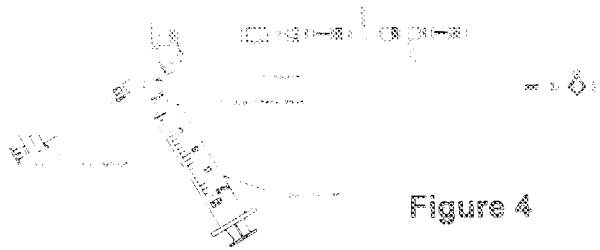


Figure 4

7. For contrast injections to check location within the vasculature, use the 20cc syringe as a reservoir syringe to store the contrast, and use the 1cc syringe as the injection syringe. By using the dual check valve, retracting the plunger of the 1cc syringe will draw contrast from the 20cc syringe, thus enabling the physician to inject contrast in very small amounts

Package Label

[redacted]

Transjugular Access Set

Contents:

1-8F PTFE Introducer with Hemostasis Valve and Sidearm

1 - 8F PTFE Catheter

1 - 5F Nylon AngiOptic™ Catheter

1 - 14g Curved Ross Needle

1 - 22g Beveled Point Needle

1 - 1cc Syringe

1 - 10cc Syringe

1 - Dual Check Valve

1 - Hemostasis Y-Adapter

CATALOG NO. /Nº de catalogue /Número de catálogo /Katalog-Nr. /Numero di catalogo /Número do catálogo /Katalognummer /カタログ番号

QUANTITY /Quantité /Cantidad /Menge /Quantità /Quantidade /Antal /数量

LOT NO. /Nº de lot /Nº de lote /Posten-Nr. /Numero di lotto /Lote nº /Lot nummer /ロット番号

STERILIZATION METHOD /Méthode de stérilisation /Método de esterilización /Sterilisationsmethode /Metodo di sterilizzazione /Método de esterilização /Steriliseringsmetod /滅菌方法

STERILIZATION DATE /Date de stérilisation /Fecha de esterilización /Sterilisationsdatum /Data di sterilizzazione /Data de esterilização /Steriliseringsdatum /滅菌年月日

EXPIRATION DATE /Date de péremption /Fecha de caducidad /Verfallsdatum /Data di scadenza /Data de expiração /Utgångsdatum /有効年月日

STERILE: Sterile unless package is opened or damaged. Single patient use: Do not resterilize.
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

STERILE · SINGLE USE · STORE IN A COOL DRY PLACE · PROTECT FROM UV LIGHT
Stérile · Destiné à un usage unique · Conserver dans un endroit sec et frais · Protéger de la lumière ultraviolette
Estéril · Úsese una sola vez · Guardar en un lugar seco y fresco · Proteger de la luz ultravioleta
Steril · Nur zum Einmalgebrauch · Kühl und trocken bewahren · Vor UV-Licht schützen
Sterile · Uso unico solamente · Riporre in un luogo fresco e secco · Protegere da la luce ultravioletto
Estéril · Use apenas uma vez · Deve ser conservado em local seco · Deve ser protegido contra radiação ultravioleta
Steril · Endast för engångsbruk · Förvaras svalt och torrt · Skyddas från ultraviolett ljus
滅菌済 再使用しないでください。 取扱説明書参照

E-Z-EM, INC. LC 340 REV. 10/93

For orders and customer service in the USA, call toll free:
ANGIODYNAMICS™
Queensbury, NY USA 1-800-[redacted] (1-800-ANGIO1 [redacted])

Premarket Notification
Transjugular Access Set

Device Description:

The ANGIODYNAMICS® Transjugular Access Set is intended to be used for transjugular access in diagnostic and interventional procedures, such as biliary drainage, liver access and biopsy, placement of vena cava filters, and cholangiography.

The ANGIODYNAMICS® Transjugular Access Set consists of the following components:

- 8 French introducer sheath with hemostasis valve
- 8 French PTFE catheter
- 5 French AngiOptic™ catheter
- 14 gauge curved Ross needle
- 21 gauge beveled tip needle

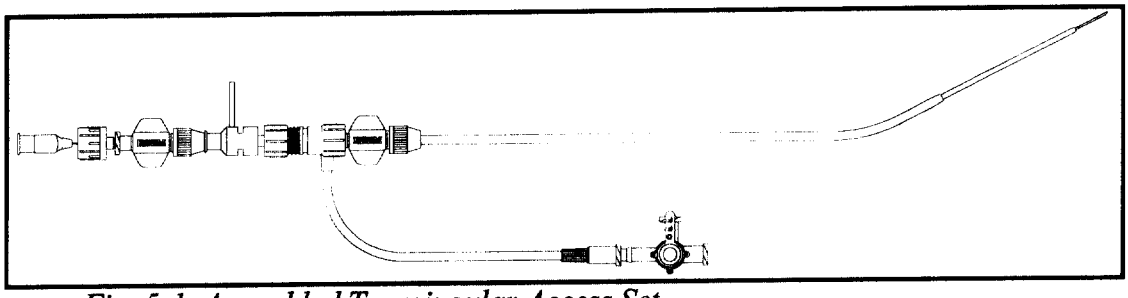


Fig. 5-1. Assembled Transjugular Access Set.

To allow for infusion of contrast agents to properly locate the device as it is advanced, the following components are also included:

- 1cc syringe, 10cc syringe, y-adapter, dual check valve

The introducer sheath consists of a 8 French I.D. x 12 French O.D. PTFE tube, 47cm in length with a nylon hub and a hemostasis valve. The intended use for the introducer sheath is to facilitate the placing of catheters into the vasculature, the same intended use as for all introducer sheaths. The introducer sheath is pictured in Fig. 5-2.

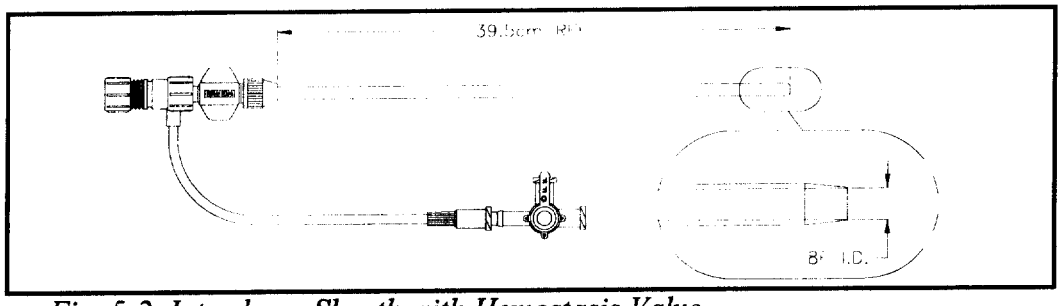


Fig. 5-2. Introducer Sheath with Hemostasis Valve.

The needle set consists of a 14 gauge blunt tipped 304 stainless steel curved Ross needle, and a 21 gauge beveled tip stainless steel needle with a nylon hub. The 14 gauge Ross needle has a torque handle / directional indicator on the hub. This handle is very useful for rotating the needle and to allow the user to know the direction in which the curve is pointing at all times. The 21 gauge needle is hollow to allow for contrast injections at any time to visualize location within the vasculature at any time throughout the procedure.

The intended use for the needle set is to act as a catheter stiffener, and to allow access to given areas within the vasculature. The needle set is pictured below in Fig. 5-3.

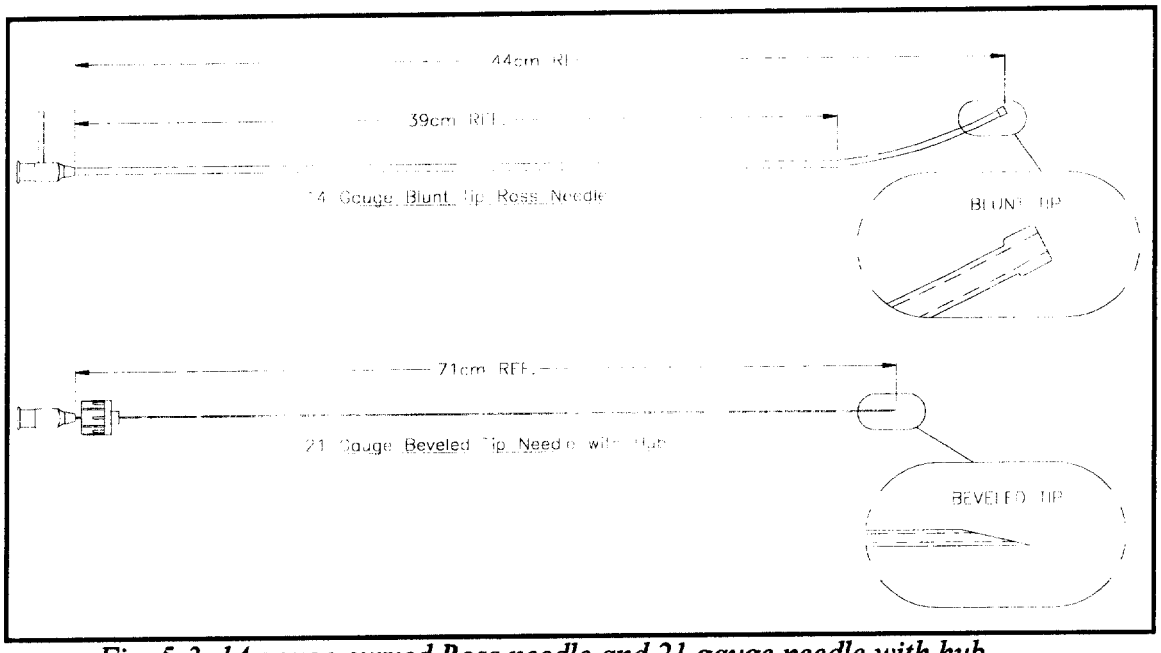


Fig. 5-3. 14 gauge curved Ross needle and 21 gauge needle with hub

The 8F catheter is comprised of a piece of PTFE tubing and a nylon catheter hub, and is intended to be used as a dilator with the Introducer Sheath (12F O.D., 8F I.D.) The 5F catheter is very similar to ANGIODYNAMICS® AngiOptic Catheter, K954423, and intended to be used to inject contrast into the patient during the procedure. The only difference between the AngiOptic Catheter used in the Transjugular Access Set and the straight

selective catheter which was found substantially equivalent in K954423 is the catheter length. The catheter in K954423 is 59.5cm in length while the 5 French straight selective catheter in K954423 is 90cm in length. The catheters are pictured in Fig. 5-4.

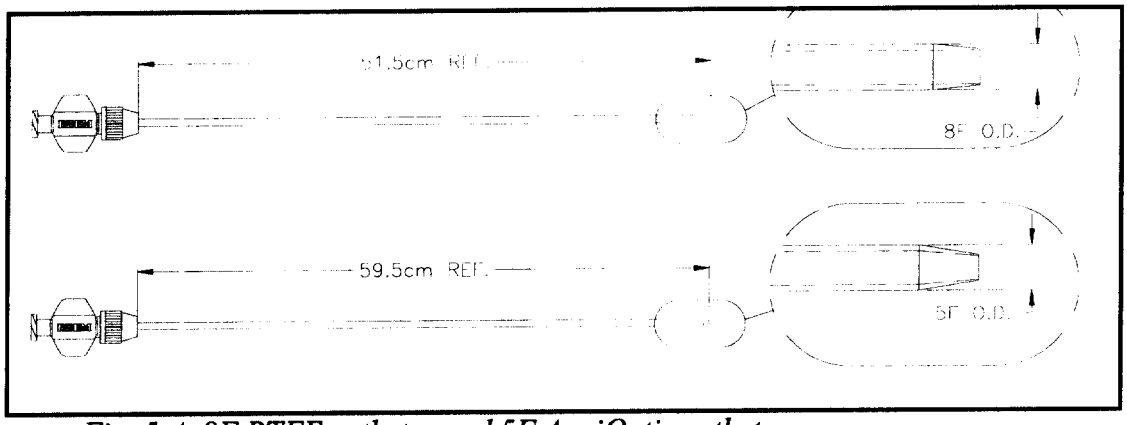


Fig. 5-4. 8F PTFE catheter and 5F AngiOptic catheter.

Tensile Testing:

(b) (4)

[redacted]

Packaging:

The ANGIODYNAMICS® Transjugular Access Set is packaged in Tyvek to polyethylene\ polyester Mylar pouches. All outer packaging materials are identical to that used for ANGIODYNAMICS® AngiOptic Angiographic Catheter, 954423.

Premarket Notification
Transjugular Access Set

Comparative Information and Substantial Equivalence:

The ANGIODYNAMICS® Transjugular Access Set is intended to be used for transjugular liver access in diagnostic and interventional procedures. This is the same intended use as the Cook Rösch-Uchida Transjugular Liver Access Set. Size and material comparison between the ANGIODYNAMICS® Transjugular Access Set and the Cook Rösch-Uchida Transjugular Liver Access Set is presented in Table 6-1.

Features	ANGIODYNAMICS® Transjugular Access Set	Cook Rösch-Uchida Transjugular Liver Access Set
Components included	Introducer Sheath with Hemostasis Valve 5F & 8F Catheter Curved stiffening needle Access needle 1cc Syringe 10cc Syringe Dual Check Valve Hemostasis Y-Adapter	Introducer Sheath with Hemostasis Valve 5F & 10F Catheter Curved stiffening needle Access needle
Introducer sheath inner diameter	8 French	10 French
Introducer sheath material	PTFE	TFE
Introducer sheath length	39.5cm	41.5cm
R/O marker on sheath	No	Yes
Catheter outer diameter	8 French, 5 French	10 French, 5 French
Catheter lengths	8F - 51.5cm 5F - 59.5cm	10F - 51cm 5F - 59cm
Catheter material	PTFE	Radiopaque TFE
Curved stiffening cannula size	14 gauge	14 gauge
Curved stiffening cannula length	44.5cm	52cm
Stiffening cannula material	Stainless steel	Stainless steel
Access needle size/style	21 gage cannula beveled point	20 gage stylet pencil point
Access needle length	69cm	62cm
Access needle material	Stainless steel	Stainless steel

Table 6-1

The primary difference between the ANGIODYNAMICS® Transjugular Access System and the Cook Rösch-Uchida Transjugular Liver Access Set is the presence of the fluid management components (dual check valve, y-adapter, 1cc syringe, 10cc syringe), and 21 gauge hollow needle to permit contrast infusion for determination of needle location as it is being advanced. This will result in easier device location and will minimize the trauma created by inaccurate advancement.

The fluid management components have been found substantially equivalent in K905447, ANGIODYNAMICS® Pulse*Spray Infusion Catheter System. The hemostasis valve was found substantially equivalent in K894446, Braun Hemostasis Valve. The 5 French AngiOptic™ catheter is very similar to the 5 French straight selective catheter, which was found substantially equivalent in ANGIODYNAMICS® AngiOptic Catheter, K954423. The only difference between the two catheters is the usable length. The 5 French straight selective catheter in K954423 is 90cm in length, while the 5 French AngiOptic™ catheter in the Transjugular Access Set is 59.5cm in length.

Pictorial comparison between the ANGIODYNAMICS® Transjugular Access Set and the Cook® Rosch-Uchida Transjugular Liver Access Set is given below in Fig. 6-1 and Fig. 6-2.

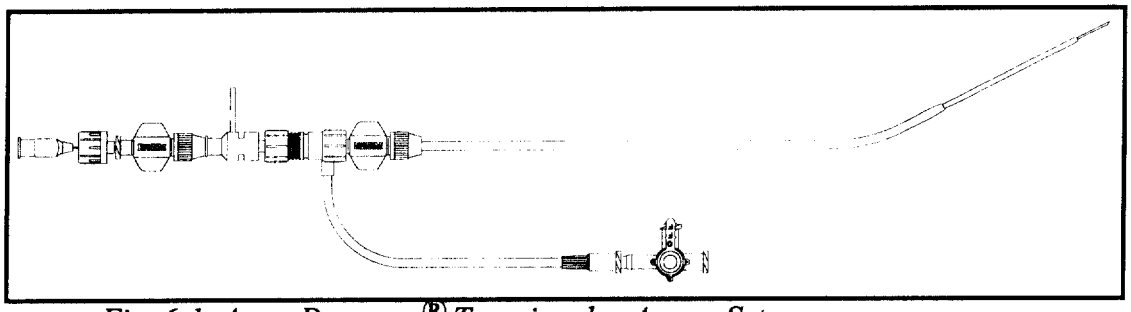


Fig. 6-1. ANGIODYNAMICS® Transjugular Access Set

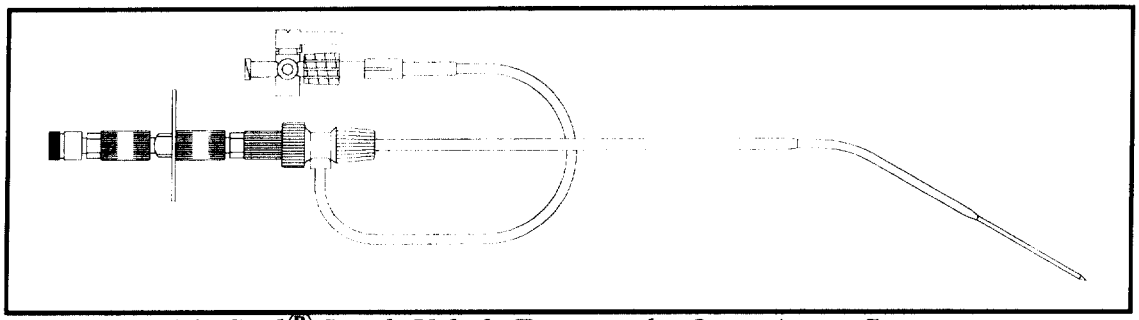


Fig. 6-2. Cook® Rosch-Uchida Transjugular Liver Access Set

Enclosed as Attachment 6-1 is a letter from Cook®, Inc. stating that the Rosch-Uchida Transjugular Liver Access Set is a modified pre-Amendment device.

Attachment 6-1

A COOK GROUP COMPANY
925 South Curry Pike P.O. Box 489
Bloomington, IN 47402 U.S.A.
Phone: 812 339 2235
Telex: 6711181 COOK UW
Telefax: 812 339-5369

COOK

Cook Incorporated

June 21, 1995

Ms. Maureen Curtin
522 Woodland Trails
East Stroudsburgh, PA 18301

RE: REQUEST FOR 510(k) SUMMARIES

Dear Ms. Curtin:

This letter follows in response to your request for 510(k) Summaries of Safety and Effectiveness for the following items:

- ☐ Colapinto transjugular cholangiography and biopsy sets
- ☐ Ring transjugular intrahepatic access set
- ☐ Rösch-Uchida transjugular liver access set

These items are modified pre-Amendment devices, which are listed under the Listing Provisions of the Medical Device Amendments of 1976. This listing was required for those items that were already on the market prior to enactment of the Amendments in 1976, which called for premarket notifications. Consequently, no 510(k) summaries are available for these devices.

Thank you for this opportunity to be of service.

Sincerely,

COOK INCORPORATED

April Lavender, RAC
Vice President
Regulatory Affairs

Premarket Notification
Transjugular Access Set

Biocompatability assessment:

Patient contact materials are:

- 304 stainless steel cannula tubing
- PTFE sheath/catheter tubing

PTFE is a very common material used in medical device applications and is well known for its biological inertness and lack of reactivity. The 304 stainless steel cannula tubing used in the 22 gauge beveled tip needle and the 14 gauge curved Ross needle is a very common material used in numerous medical devices throughout the industry. The 5 French AngiOptic Catheter biocompatibility test results from K954423 is included with all other biocompatibility test results in Attachment 7-1.

Test	Result
(b) (4)	[redacted]

Attachment 7-1

(b) (4) Cytotoxicity Test

(b) (4) Cytotoxicity Test

(b) (4) Cytotoxicity Test

(b) (4) Cytotoxicity Test

(b) (4) Cytotoxicity Test

(b) (4) Cytotoxicity Test

(b) (4) Hemolysiss Test - In Vitro Procedure

(b) (4) Hemolysiss Test - In Vitro Procedure

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(b) (4) Hemolysiss Test - In Vitro Procedure

(b) (4) Hemolysiss Test - In Vitro Procedure

(b) (4) Pyrogen Study

(b) (4) Pyrogen Study

(b) (4) Pyrogen Study

(b) (4) Pyrogen Study

(b) (4) Pyrogen Study

(b) (4) Pyrogen Study

(b) (4) Pyrogen Study

(b) (4) Primary Skin Irritation Test

(b) (4) Primary Skin Irritation Test

(b) (4) Primary Skin Irritation Test

(b) (4) Primary Skin Irritation Test

(b) (4) Primary Skin Irritation Test

(b) (4) Primary Skin Irritation Test

(b) (4) Primary Skin Irritation Test

(b) (4) Pyrogen Test

Pyrogen Test Specification

(b) (4)

(b) (4) USP Intracutaneous Toxicity Test

(b) (4) USP Intracutaneous Toxicity Test

(b) (4) Hemolysis Test In Vitro

(b) (4) USP Muscle Implantation Study

(b) (4) USP Muscle Implantation Study

(b) (4) USP Muscle Implantation Study

(b) (4) USP Muscle Implantation Study

(b) (4) USP Muscle Implantation Study

(b) (4) USP Muscle Implantation Study

(b) (4) Physico Chemical Tests

(b) (4) USP Systemic Toxicity Study

(b) (4) USP Systemic Toxicity Study

(b) (4) USP Systemic Toxicity Study

(b) (4) USP Systemic Toxicity Study

(b) (4) USP Systemic Toxicity Study

(b) (4) USP Systemic Toxicity Study

(b) (4) Microsome Mutagenicity Assay

(b) (4) Microsome Mutagenicity Assay

(b) (4) Microsome Mutagenicity Assay

(b) (4) Microsome Mutagenicity Assay

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(b) (4) Microsome Mutagenicity Assay

(b) (4) Primary Skin Irration Test

(b) (4) Primary Skin Irration Test

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(b) (4) Primary Skin Irration Test

(b) (4) Primary Skin Irration Test

ZEUS

MEDICAL DIVISION
FAX COVER SHEET

PAGE 1 OF 10 DATE: 7/1/96

TO: Angio Dynamics FAX: 518-798-3625

ATTN: Mark Steininger FROM: Jeff Prioreschi

COMMENTS:

ZEUS INDUSTRIAL PRODUCTS, INC.
501 BOULEVARD, SE, P.O. BOX 2167, ORANGEBURG, SOUTH CAROLINA 29116-2167
TOLL FREE: 800-526-3842 • PHONE: 803-531-2174 • FAX: 803-531-9244

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Tubing Cerification

(b) (4) Tubing Cerification

Premarket Notification
Transjugular Access Set

Sterilization Information:

(b) (4)

[redacted]

Pyrogen Testing:

(b) (4)

[redacted]

Premarket Notification
Transjugular Access Set

Product Drawings:

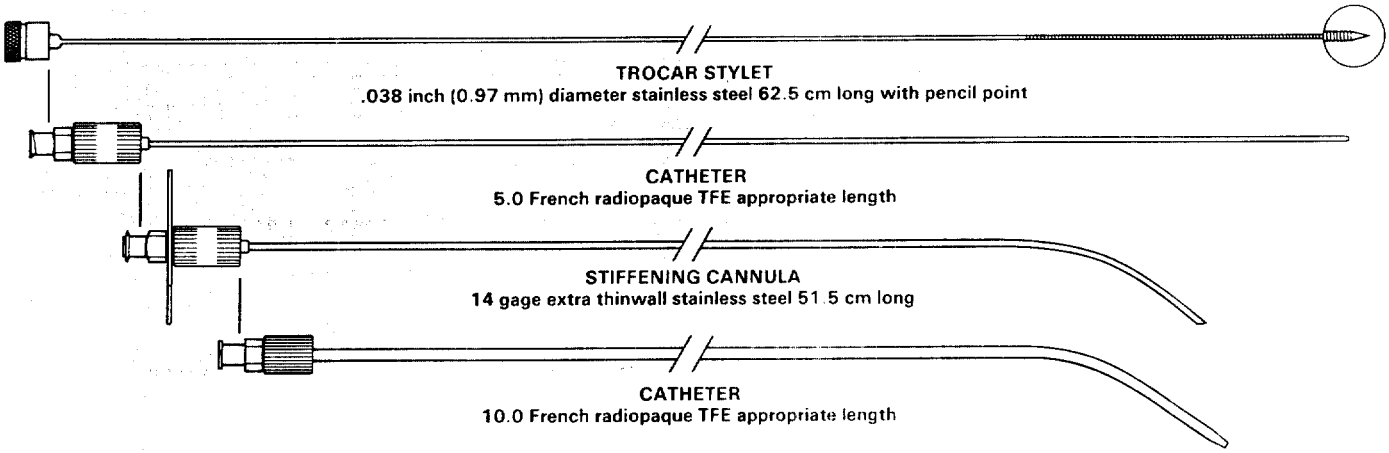
(b) (4) Drawing

Premarket Notification
Transjugular Access Set

Predicate Device Labeling:

RÖSCH-UCHIDA TRANSJUGULAR LIVER ACCESS SET

Used for transjugular liver access in diagnostic and interventional procedures. The radiopaque marker on the distal tip of the sheath enhances visualization during procedural use. Stiffening cannula provides added support during liver capsule puncture. Trocar stylet facilitates uncomplicated puncture. Supplied sterile in peel-open packages. Intended for one-time use.

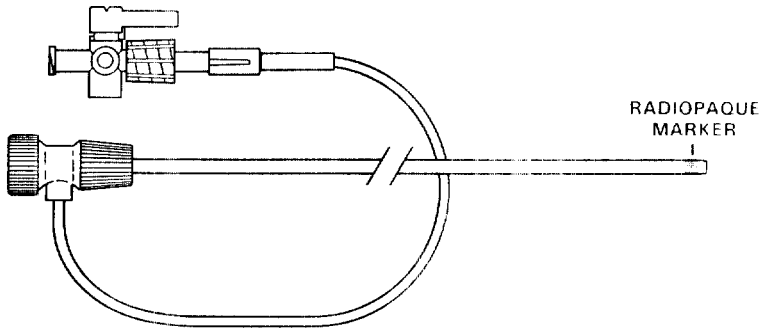


TROCAR STYLET
.038 inch (0.97 mm) diameter stainless steel 62.5 cm long with pencil point

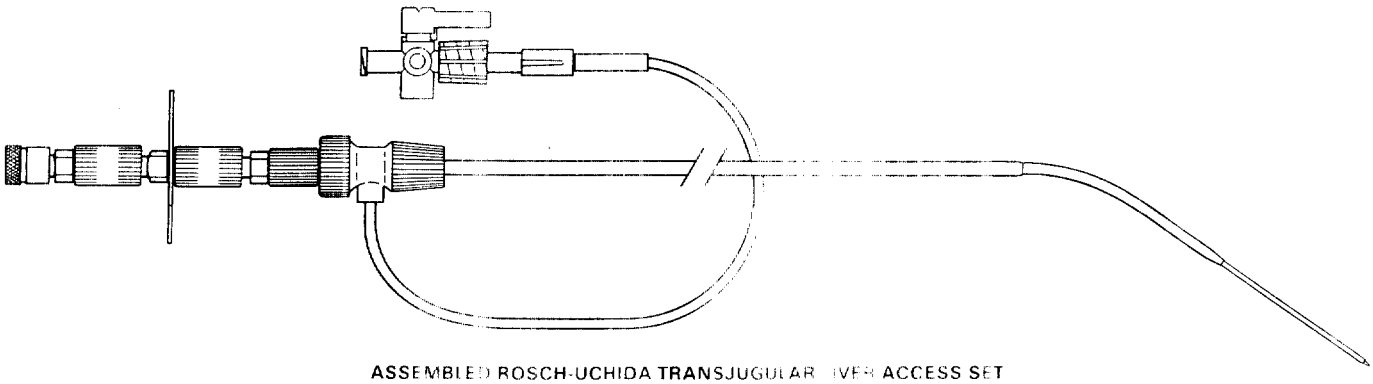
CATHETER
5.0 French radiopaque TFE appropriate length

STIFFENING CANNULA
14 gage extra thinwall stainless steel 51.5 cm long

CATHETER
10.0 French radiopaque TFE appropriate length



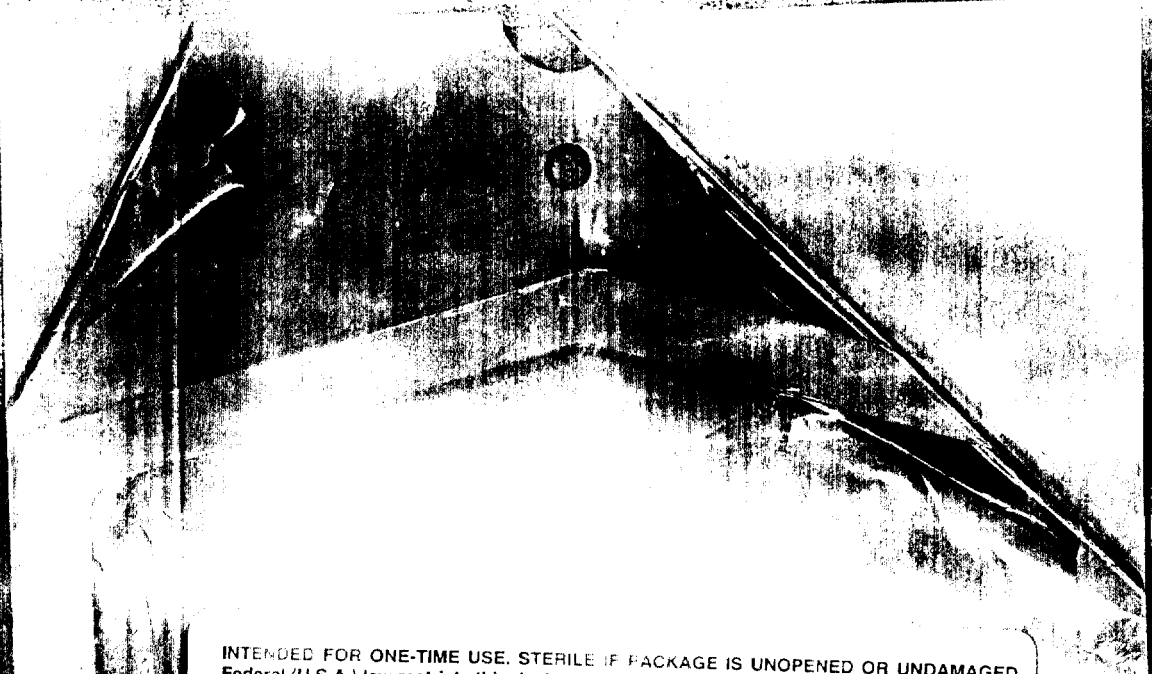
CHECK-FLO® III INTRODUCER
10.0 French radiopaque 41 cm long



ASSEMBLED ROSCH-UCHIDA TRANSJUGULAR LIVER ACCESS SET

SET ORDER NUMBER	TROCAR STYLET Diameter	TROCAR STYLET Length	STIFFENING CANNULA Gage extra-thinwall	STIFFENING CANNULA Length
RUPS-100	.038 inch (0.97 mm)	62.5 cm	14	51.5 cm

REFERENCES: Page 283, R-BD32, R-BD36



INTENDED FOR ONE-TIME USE. STERILE IF PACKAGE IS UNOPENED OR UNDAMAGED.
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

REORDER# RUPS-100

ROSCH-UCHIDA

TRANSJUGULAR LIVER ACCESS SET

INCLUDES:

TRANSJUGULAR NEEDLE 14 GA.
5CM LONG

* DILATOR, 12.0 FR 20CM LONG

* TFE CATHETER, 10 FR (USED WITH 14 GA. TRANSJUGULAR NEEDLE)

* TFE CATHETER, 5.2FR (USED WITH .038 IN. DIA. FLEXIBLE TIP NEEDLE, 62.5CM LONG

* CHECK-FLO™ II RUPS INTRODUCER 10 FR., 41CM LONG SHEATH WITH RADIOPAQUE BAND

LOT NO 6150184
DO NOT USE AFTER 02/95
QUICK REORDER# 187438

RC 994

Cook Group Company
P.O. Box 489 Bloomington, IN 47402 USA

COOK®