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(71) Applicant: BECTON, DICKINSON AND COMPANY
[US/US]; One Becton Drive, Franklin Lakes, NJ 07417-
1880 (US).

(72) Inventors: GAWRELUK, Craig, N.; 8036 North Long
Rifle Road, Park City, UT 84098 (US). CASTRO, Cyn-
thia, A.; 8330 South 1050 East, Sandy, UT 84094 (US).
HARDING, Weston, F.; 2421 North 910 West, Lehi, UT

84043 (US). JOHNSON, Steven, W.; 7684 South 2250
West, West Jordan, UT 84084 (US). PARRIS, Wayne,
M.; 14007 South Point Hills Cove, Draper, UT 84020
(US). GUO, Lantao; 869 Park School Road, Draper, UT
84020 (US). LARSEN, Michael, C.; 9860 Heytesbury
Lane, Sandy, UT 84092 (US).

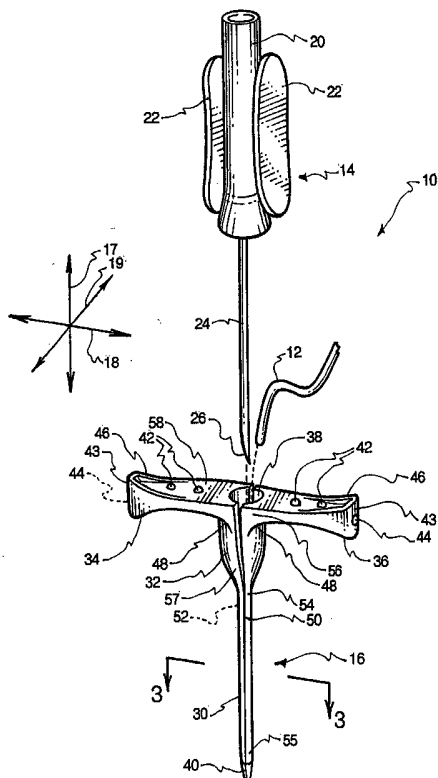
(74) Agent: MURTHA, James, J.; Becton, Dickinson and
Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1880
(US).

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LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
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(54) Title: CATHETER SLEEVE ASSEMBLY AND ONE STEP INJECTION MOLDING PROCESS FOR MAKING THE SAME



(57) Abstract: An enhanced catheter introducer (10) and method for making the same are disclosed. The catheter (10) introduced may have a splittable sleeve assembly (16) configured to be inserted into a blood vessel with a cannula (24). The cannula (24) may then be removed, and a catheter (12) may be inserted into the sleeve assembly (16). The sleeve assembly (16) may be removed from the catheter (12) by pulling handles (34, 36) of the sleeve assembly (16) in different directions to split the sleeve assembly (16) into two pieces. The sleeve assembly (16) may have failure zones (50, 52) that enable the sleeve assembly (16) to be easily split; the failure zones (50, 52) may take the form of thinned regions (50, 52) running along the length of the sleeve assembly (16). The sleeve assembly (16) may be injection molded with a single step by injecting flows of molten plastic into a cavity of a mold (110) such that the flows converge into an even distribution about the circumference of the sleeve (30). The mold (110) may have a core pin designed to fit into the cavity. Through the use of the even distribution of flows, the core pin (140) may seat within the cavity in an un- tensioned manner.

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European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,
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INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER

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B29C45/16 B29C45/26

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 027 480 A (DAVIS BRYAN G ET AL) 22 February 2000 (2000-02-22) column 1, line 16-28; figures 1-3,6-10 column 1, line 54-58 column 2, line 25-50 column 3, line 1-32 column 4, line 6-23 column 4, line 47-53 column 4, line 66 -column 5, line 30 column 5, line 49-54 ---	1-7, 15-17,20
X	US 5 221 263 A (SINKO GEORGE E ET AL) 22 June 1993 (1993-06-22) column 1, line 33 -column 2, line 46; figures 1-8 column 3, line 6-34 column 3, line 60 -column 4, line 8 --- -/--	1-6, 15-17

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

5 February 2003

Date of mailing of the international search report

20.05.03

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Brumme, I

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/35380

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 743 882 A (LUTHER RONALD B) 28 April 1998 (1998-04-28) column 3, line 44-55; figures 1,4,6A-6D column 1, line 61-16 -column 2 ---	1-6,16, 17
A	EP 0 761 250 A (TARGET THERAPEUTICS INC) 12 March 1997 (1997-03-12) column 12, line 50 -column 13, line 18 ---	8,11-14
A	US 5 735 819 A (ELLIOTT GREGORY D) 7 April 1998 (1998-04-07) column 4, line 57 -column 5, line 16; figure 1 -----	18,19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/35380

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: 9, 10
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-8, 11-20

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 9, 10

Present claims

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-8, 11-20

Defining a catheter introducer having a canula and a sleeve formed of plastic. The sleeve having a tubular shape and providing a hub and a two handles extending in opposite directions.

2. Claims: 21-25 and 51-63

Defining a sleeve for a catheter introducer and a method for injection molding a sleeve for a catheter introducer. The method for injection molding the sleeve providing a mold with a cavity dimensioned to produce a sleeve wherein the cavity contains a sleeve annulus.

3. Claims: 26-50 and 64-68

Defining a mold for manufacturing a sleeve assembly for a catheter introduce. The mold providing a cavity dimensioned to produce a sleeve assembly wherein the cavity has a sleeve portion and a hub portion. A method for injection molding and for forming a sleeve assembly for a catheter introducer. The method providing a mold with a cavity dimensioned to produce a sleeve assembly wherein the cavity has a sleeve portion and a hub portion.

4. Claims: 69-72

Defining a method for forming a tip for a sleeve of a catheter introducer.

5. Claims: 73-85

A catheter introducer defined by its manufacturing process.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/35380

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6027480	A	22-02-2000	AU 8510598 A	01-03-1999
			EP 1003586 A1	31-05-2000
			JP 2002517263 T	18-06-2002
			WO 9907431 A1	18-02-1999
			US 6273871 B1	14-08-2001

US 5221263	A	22-06-1993	AT 175582 T	15-01-1999
			AU 4101493 A	03-03-1994
			CA 2141295 A1	17-02-1994
			DE 69323084 D1	25-02-1999
			DE 69323084 T2	26-08-1999
			EP 0652782 A1	17-05-1995
			JP 8501708 T	27-02-1996
			WO 9403221 A1	17-02-1994

US 5743882	A	28-04-1998	NONE	

EP 0761250	A	12-03-1997	US 6096022 A	01-08-2000
			AU 686518 B2	05-02-1998
			AU 6437396 A	01-05-1997
			CA 2184502 A1	01-03-1997
			EP 0761250 A1	12-03-1997
			JP 3198057 B2	13-08-2001
			JP 9164207 A	24-06-1997
			NO 963625 A	03-03-1997

US 5735819	A	07-04-1998	AU 727857 B2	04-01-2001
			AU 3894797 A	25-02-1998
			EP 0923400 A1	23-06-1999
			JP 2000515405 T	21-11-2000
			WO 9805373 A1	12-02-1998
