

COMMONWEALTH OF AUSTRALIA
PATENTS ACT 1952
APPLICATION FOR A STANDARD PATENT

Schneider (Europe) AG, of Scharenmoosstrasse 117, 8052 Zurich, SWITZERLAND, hereby apply for the grant of a standard patent for an invention entitled:

Introduction Valve in a Tube Connecting Piece for a
Catheter Arrangement

which is described in the accompanying complete specification.

Details of basic application(s):-

| <u>Basic Applic. No:</u> | <u>Country:</u> | <u>Application Date:</u> |
|--------------------------|-----------------|--------------------------|
| 1278/88-1 | CH | 7 April 1988 |

The address for service is:-

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Patent Attorneys
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DATED this TENTH day of APRIL 1989

Schneider (Europe) AG

By:

Registered Patent Attorney

TO: THE COMMISSIONER OF PATENTS
OUR REF: 92209
S&F CODE: 60030

5006674 10/04/89

616252

PC7362

SPRUSON & FERGUSON

Australia

Patents Act 1990

NOTICE OF ENTITLEMENT

In support of the convention application made for a patent for an invention entitled:

Introduction Valve in a Tube Connecting Piece for a Catheter Arrangement

I, Allen J. Spiegel, care of Schneider (Europe) AG, Scharenmoosstrasse 117, 8052 Zurich, Switzerland do solemnly and sincerely declare as follows:

1. I am authorised by Schneider (Europe) AG, the applicant for the patent to make this declaration on its behalf.
2. The basic application as defined by Section 141 of the Act was made in Switzerland on 7 April 1988 by Schneider-Shiley AG.
3. Werner Niederhauser, of Baerenbohlstrasse 31, 8046 Zurich, Switzerland, is the actual inventor of the invention and the facts upon which the applicant is entitled to make the application are as follows:-

Schneider (Europe) AG is the assignee of the invention from Schneider-Shiley AG, Schneider-Shiley AG being entitled by contract of employment between the inventor as employee and Schneider-Shiley AG as employer, as a person who would be entitled to have the patent assigned to it if a patent were granted upon an application made by the inventor.

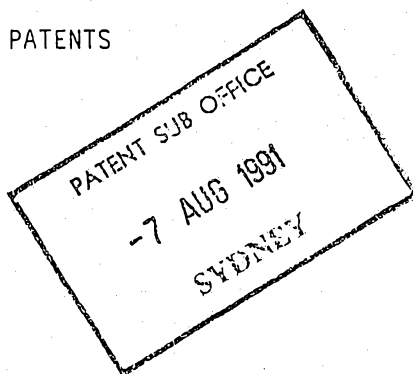
4. The basic application referred to in paragraph 2 of this Declaration was the first application made in a Convention country in respect of the invention(s) the subject of the application.

DECLARED at New York, this 25 day of July 19 91
New York SCHNEIDER (EUROPE) AG

.....
Signature of Declarant(s)

TO: THE COMMISSIONER OF PATENTS
AUSTRALIA

ALLEN J. SPIEGEL
DIRECTOR OF FOREIGN PATENTS



TMS/799T

(12) PATENT ABRIDGMENT (11) Document No. AU-B-32626/89
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(54) Title
INTRODUCTION VALVE IN A TUBE CONNECTING PIECE FOR A CATHETER ARRANGEMENT

International Patent Classification(s)

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(51)⁵ **A61M 039/00**

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(56) Prior Art Documents
US 4252122
EP 190388

(57) Claim

1. An introducer valve body, for use within a connecting housing having a longitudinal passageway, for sealing the passageway and for sealing an elongated guidewire or catheter element which may be inserted within the passageway, comprising:

a generally cylindrical elastomeric body having a proximal end, a distal end, a central axis and a central longitudinal opening therein, and further comprising an elastomeric ring which circumscribes the valve body to facilitate the sealing of the valve;

said opening having a proximal aperture tapering inwardly to the central axis and having a distal aperture tapering inwardly to the central axis, and adapted to receive the elongated element, and wherein the exterior surface of the body tapers inwardly from said proximal end and tapers inwardly from said distal end generally parallel respectively with said proximal and distal apertures.

S & F Ref: 92209

FORM 10

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

COMPLETE SPECIFICATION

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(ORIGINAL)

FOR OFFICE USE:

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Complete Specification Lodged:
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Related Art:

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Complete Specification for the invention entitled:



Introduction Valve in a Tube Connecting Piece for a
Catheter Arrangement

The following statement is a full description of this invention, including the
best method of performing it known to me/us

P.C. 7362

INTRODUCER VALVE FOR A CATHETER ARRANGEMENT

ABSTRACT

5 An introducer valve has a connecting housing
enclosing a generally cylindrical elastomeric valve
body having a proximal end, a distal end, a central
axis, and a central longitudinal opening. The central
opening has a proximal aperture tapering inwardly to
the central axis and has a distal aperture tapering
inwardly to the central axis, and is adapted to receive
10 an elongated guidewire or catheter element. The valve
body has an exterior surface which tapers from the
proximal end inwardly and from the distal end inwardly
generally parallel with the respective apertures (in a
somewhat hourglass configuration). The central opening
15 of the valve body is normally sealed closed, and
further surrounds and seals a penetrating catheter
which is introduced or changed within the valve. The
valve further comprises an elastomeric ring which
circumscribes the center of the valve body. This ring
20 facilitates the compressive sealing of the central
opening and particularly facilitates liquid-tight
sealing with penetrating elements having greatly
differing diameters of about 1 mm to about 6 mm.

INTRODUCER VALVE FOR A CATHETER ARRANGEMENT

The invention relates to a valve for introducing a guidewire, dilator, or catheter into a vessel of a patient while maintaining a liquid seal at all times.

5 An introducer valve of the prior art is known in which an O-ring of silicon rubber is enclosed in a housing through which a carrier tube of a catheter is inserted for the purpose of providing a liquid-tight seal. In another known tube connecting introducer valve, there is similarly arranged a radial seal which surrounds an elongated guide element, which
10 is substantially thinner than the carrier tube, for the purpose of providing a pressure-tight seal. Also known, is an introducer valve having several flat sealing elements arranged one behind the other with different sized openings. In this stated arrangement, each sealing element is tailored to a certain diameter such that only one of these
15 surrounding elements seals the elongated element which is inserted through the valve.

In practice, these valves often prove not to be liquid-tight. These prior art sealing elements also demand a high level of precision to fabricate and assemble and therefore are relatively expensive to
20 manufacture.

It is the object of the present invention to overcome or substantially ameliorate the above disadvantages.

There is disclosed herein an introducer valve body, for use within a connecting housing having a longitudinal passageway, for sealing the
25 passageway and for sealing an elongated guidewire or catheter element which may be inserted within the passageway, comprising:

a generally cylindrical elastomeric body having a proximal end, a distal end, a central axis and a central longitudinal opening therein, and further comprising an elastomeric ring which circumscribes the valve
30 body to facilitate the sealing of the valve;

said opening having a proximal aperture tapering inwardly to the central axis and having a distal aperture tapering inwardly to the central axis, and adapted to receive the elongated element, and wherein the exterior surface of the body tapers inwardly from said proximal end
35 and tapers inwardly from said distal end generally parallel respectively with said proximal and distal apertures.

Since the introducer valve of the present invention typically has only one sealing element, the assembly is substantially easier and more reliably accomplished than with multiple elements of the prior art valve. The valve is advantageous in that the seal is formed with
5 penetrating guides and catheters ranging from about 1 mm to about 6 mm in a continuous and self-adjusting manner and the penetrating elements can be inserted using relatively very little force.

Further characteristics and advantages of the invention will become apparent from the description of preferred, but not exclusive,
10 embodiments of the invention, given only by way of non-limitative

examples, which make reference to the accompanying drawings in which:

Figure 1 is a side elevational view of the introducer valve and catheter arrangement;

5 Figure 2 is an exploded longitudinal sectional view of Figure 1 illustrating the internal components of the valve;

Figure 3a is an enlarged view of the valve body of Figure 2 further including an inserted small guidewire;

10 Figure 3b is a top plan view of the valve body illustrated in Figure 3a; and

Figure 3c is similar to Figure 3a further illustrating a catheter inserted through the valve body of the present invention.

15 As shown in the figures, the valve and catheter arrangement has a tube connecting housing 21 which has an introduction tube 2 fixed thereto typically by means of a union nut 17 and which allows the introduction of a guidewire 18 (see Figures 3a and 3b), into the vessel of the patient. The tube connecting housing 21 has a cylindrical enclosure 5 having a longitudinal passageway 12 which is circular in cross-section. An elastomeric sealing element is provided by installing a valve body 7 within enclosure 5 which is retained by a casing 6 and secured at the proximal end by an end cap 4. The enclosure 5 includes a lateral passage 14 communicating with passageway 12 and which has a tube 3 extending from the passage 14 to provide secondary access to the central passageway, for example, for actuating an expansion balloon connected to a suction and pressure pump.

20 As shown, (particularly in Figure 3a), the valve body 7 has a proximal end 8, a distal end 8' and a central longitudinal passageway 20. The longitudinal passageway 20 includes a proximal aperture tapering

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inwardly to the central axis and has a distal aperture tapering inwardly to the central axis which form generally conical surfaces 10 at each end interconnected by a 1 mm central passage along the central axis. A conical aperture tapered at an angle of about 20° relative to the central longitudinal axis was found to be quite suitable. The narrowest point 11 along the central passageway 20 is about 1 mm in diameter in the free preinstalled condition. The exterior surface 22 of valve body 7 is also tapered inwardly from the proximal and distal ends and are essentially parallel to the respective inner surfaces 10, (in a somewhat hourglass configuration) such that the valve body 7 has generally uniform wall thickness. The proximal and distal ends of valve body 7 are generally perpendicular to the respective inner surfaces thereby forming generally frustoconically shaped end surfaces 8 and 8'. The valve body 7 is preferably formed of silicon rubber having a shore hardness of about 20 to 40 and more preferably of about 20. The valve body can of course be molded from a variety of other elastomeric materials.

The length of the valve body 7 and the length of the passageway 12 within enclosure 5 are configured to snugly engage the valve body 7 within the housing 21. The passageway 12 includes an inward shoulder 13 adapted to engage the distal end 8', and the casing 6 includes a surface 9 adapted to engage the proximal end 8 of the valve body 7 when the end cap 4 is secured. The installation of the valve body 7 into the housing enclosure 5 tends to naturally compress the body to further facilitate the sealing action of the valve.

Referring particularly to Figures 3a and 3c, as a penetrating element such as guidewire 18 is inserted into the valve body, the central area expands resulting

in a wide contact surface between the valve body and the guidewire providing a reliable liquid-tight seal. As a substantially larger diameter tube 19 (Figure 3c) for example having a diameter of 6 mm, is pushed onto guidewire 18, then a comparatively wider contact surface results at 11 between valve body 7 and the tube 19 which expands radially outward. Since the valve body 7 is supported only at the distal end 8' and the proximal end 8, it can be displaced in the central area without generating high radial forces and with controlled deformation. The comparatively thick tube 19 can therefore be shifted in the longitudinal direction with little friction or resistance from the valve body 7.

The valve body 7 is preferably symmetrical in relation to its longitudinal axis, to exert equal push and pull forces upon the catheter and to ensure that the valve body cannot be incorrectly assembled. However, special circumstances may require that the apertures have different angles and do not converge at the center of the valve body.

A further or second embodiment is also illustrated by referring to Figures 3a and 3c in which the valve body of the first embodiment is enhanced by the addition of an elastomeric ring 23 which circumscribes the exterior surface of the valve body. The elastomeric ring 23 is particularly useful in procedures requiring penetrating elements having greatly differing diameters. Experiments have shown that it is possible to avoid cracks forming in the valve body 7 having the ring, even under very heavy stresses and radial expansion of up to 400 percent. The ring can be made of silicon rubber and circumscribe valve body 7 as illustrated at its narrowest central point. The ring supports the immediate contraction of

the valve body to seal the valve when the catheter is being changed. The elastomeric ring is particularly advantageous in that the valve body 7 can be manufactured from less elastic materials such as polyurethane, in which case the elastomeric ring facilitates the sealing action of the valve body.

The foregoing embodiments provide examples of an introducer valve which operates reliably with various sized penetrating elements. The valve is relatively easy to fabricate and reliable to assemble and is thus extremely cost-effective.

The claims defining the invention are as follows:

1. An introducer valve body, for use within a connecting housing having a longitudinal passageway, for sealing the passageway and for sealing an elongated guidewire or catheter element which may be inserted within the passageway, comprising:

a generally cylindrical elastomeric body having a proximal end, a distal end, a central axis and a central longitudinal opening therein, and further comprising an elastomeric ring which circumscribes the valve body to facilitate the sealing of the valve;

said opening having a proximal aperture tapering inwardly to the central axis and having a distal aperture tapering inwardly to the central axis, and adapted to receive the elongated element, and wherein the exterior surface of the body tapers inwardly from said proximal end and tapers inwardly from said distal end generally parallel respectively with said proximal and distal apertures.

2. The introducer valve body of claim 1 where said ring is positioned to circumscribe the center of said body.

3. An introducer valve body substantially as hereinbefore described with reference to the accompanying drawings.

DATED this SECOND day of MAY 1991

Schneider (Europe) AG

Patent Attorneys for the Applicant

SPRUSON & FERGUSON



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