(CONVENTION. By one or more persons and/or a Company.) Form 4

COMMONWEALTH OF AUSTRALIA

Patents Act 1952-1969

60422

CONVENTION APPLICATION FOR A PATENT

(1) Here insert (in full) Name or Names of Applicant or Applicants, followed by Address (es).

~~I~~/We (1) PORTEX, INC.
of 42 Industrial Way, Wilmington,
Massachusetts 01887,
United States of America.

(2) Here insert Title of Invention.

hereby apply for the grant of a Patent for an invention entitled: (2)
TRACHEOSTOMY TUBE WITH RING PULL REMOVABLE INNER CANNULA

(3) Here insert number(s) of basic application(s)

which is described in the accompanying complete specification. This application is a Convention application and is based on the application numbered (3)
059,078

(4) Here insert Name of basic Country or Countries, and basic date or Dates

for a patent or similar protection made in (4) United States of America
on 8th June 1987

APPLICATION ACCEPTED AND AMENDMENTS
ALLOWED 14-11-90

~~My~~/Our address for service is Messrs. Edwd. Waters & Sons, Patent Attorneys, 50 Queen Street, Melbourne, Victoria, Australia.

M000140 07/06/88 DATED this 6th day of June 1988

(5) Signature (s) of Applicant (s) or Seal of Company and Signatures of its Officers as prescribed by its Articles of Association.

(5)

PORTEX, INC.

by

Stephen K.Plymin

Registered Patent Attorney

AUSTRALIAN PATENT OFFICE

THE COMMISSIONER OF PATENTS.

Edwd. Waters & Sons,

AUSTRALIA

Patents Act

DECLARATION FOR A PATENT APPLICATION

▼ **INSTRUCTIONS**

(a) Insert "Convention" if applicable

(b) Insert FULL name(s) of applicant(s)

In support of the (a) Convention application made by (b)

PORTEX, INC.

(c) Insert "of addition" if applicable

(d) Insert TITLE of invention

(hereinafter called "applicant(s) for a patent (c) for an invention entitled (d)

TRACHEOSTOMY TUBE WITH RING PULL REMOVABLE INNER CANNUAL

(e) Insert FULL name(s) AND address(es) of declarant(s) (See headnote*)

I/We (e) RICHARD F. ROSCOE

42 Industrial Way, Wilmington, Massachusetts 01887, United States of America

do solemnly and sincerely declare as follows:

1. ~~I am/We are the applicant(s)~~
(or, in the case of an application by a body corporate)
1. I am/We are authorized to make this declaration on behalf of the applicant(s).
2. ~~I am/We are the actual inventor(s) of the invention~~
~~The~~

(f) Insert FULL name(s) AND address(es) of actual inventor(s)

2. (f) DENIS LaBOMBARD, 7 Boardman Street, Georgetown, Massachusetts 01833, United States of America

(g) Recite how applicant(s) derive(s) title from actual inventor(s) (See headnote**)

is/~~are~~ the actual inventor(s) of the invention and the facts upon which the applicant(s) is/~~are~~ entitled to make the application are as follows:

(g) The Applicant is the assignee of the said acutal inventor.

*(**Note:** Paragraphs 3 and 4 apply **only** to Convention applications)*

(h) Insert country, filing date, and basic applicant(s) for the/or EACH basic application

3. The basic application(s) for patent or similar protection on which the application is based is/are identified by **country, filing date, and basic applicant(s)** as follows:

(h) United States of America, 8th June 1987 by DENIS LaBOMBARD

4. The basic application(~~s~~) referred to in paragraph 3 hereof was/~~were~~ the first application(s) made in a Convention country in respect of the invention the subject of the application.

(k) Insert PLACE of signing

(l) Insert DATE of signing

(m) Signature(s) of declarant(s)

X Declared at (k) Portex, Inc. Wilmington, Mass. 01887, USA

X Dated (l) August 23, 1988

X (m) Richard F. Roscoe

Note: No legalization or other witness required

To: The Commissioner of Patents

(12) PATENT ABRIDGMENT (11) Document No. AU-B-17444/88
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 606422

(54) Title
TRACHEOSTOMY TUBE WITH RING PULL REMOVABLE INNER CANNULA

International Patent Classification(s)
(51)[4] A61M 016/04

(21) Application No. : 17444/88 (22) Application Date : 07.06.88

(30) Priority Data

(31) Number	(32) Date	(33) Country
059078	08.06.87	US UNITED STATES OF AMERICA

(43) Publication Date : 08.12.88

(44) Publication Date of Accepted Application : 07.02.91

(71) Applicant(s)
PORTEX, INC.

(72) Inventor(s)
DENIS LABOMBARD

(74) Attorney or Agent
WATERMARK PATENT & TRADEMARK ATTORNEYS, Locked Bag 5, HAWTHORN VIC 3122

(56) Prior Art Documents
US 4315505
US 4009720
US 3334631

(57) Claim

1. A removable cannula system comprising:

an outer cannula having a first and second end;

an inner cannula having a first and second end, said inner cannula being interconnectable inside said outer cannula at said second end ;

first locking means disposed inside said outer cannula at said second end and second locking means disposed at said second end of said inner cannula for interconnecting said inner cannula inside said outer cannula; and,

grasping means for facilitating withdrawal of said inner cannula from said outer cannula, said grasping means including an annular ring with a hinge means connecting said annular ring to said inner cannula, said annular ring being alignable with an opening of said outer cannula at said second end and easily accessible to the fingers to be unfolded for pulling said inner cannula from said outer cannula.

.../2

4. A tracheostomy tube comprising:

an outer cannula having a first and second end;

a tubular connector member integral with said outer cannula at said second end;

a removable inner cannula removably disposed inside said outer cannula, said inner cannula having a first and second end, said inner cannula being interlockable inside said connector member at said second end;

first locking means disposed inside said tubular connector member and second locking means disposed at said second end of said inner cannula for interconnecting said inner cannula inside said connector member; and

grasping means for facilitating withdrawal of said inner cannula from said outer cannula, said grasping means including an annular ring with a hinge means connecting said annular ring to said inner cannula, said annular ring being alignable with an opening of said tubular connector member and easily accessible to the fingers to be unfolded for pulling said inner cannula from said outer cannula.

Form 10

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952-69

COMPLETE SPECIFICATION

(ORIGINAL)

606422

Class Int. Class

Application Number:
Lodged:

Complete Specification Lodged:
Accepted:
Published:

Priority :

Related Art :

This document contains the amendments made under Section 49 and is correct for printing.

Name of Applicant : PORTEX, INC.

Address of Applicant : 42 Industrial Way,
Wilmington,
Massachusetts 01887,
United States of America.

Actual Inventor: DENIS LaBOMBARD

Address for Service : EDWD. WATERS & SONS,
50 QUEEN STREET, MELBOURNE, AUSTRALIA, 3000.

Complete Specification for the invention entitled:

TRACHEOSTOMY TUBE WITH RING PULL REMOVABLE INNER CANNULA

The following statement is a full description of this invention, including the best method of performing it known to :- US

AUSTRALIAN PATENT OFFICE

TRACHEOSTOMY TUBE WITH RING PULL REMOVABLE INNER CANNULA

Background of the Invention

The present invention relates to respiratory circuits and particularly to tracheostomy tubes comprising of an outer constant radius cannula and a removable inner cannula.

Tracheostomy tubes with removable inner cannula are well known in the prior art. When a two part tracheostomy tube is placed in the patients trachea, if the patients tracheostomy should become occluded by mucus or phlegm, the tracheostomy tube airway can be cleaned by removing the inner cannula. After being cleaned, the inner cannula can be placed inside the outer cannula of the tracheostomy tube which remains in place in the trachea.

Various means of connecting the inner cannula to the tracheostomy tube and connecting the tracheostomy tube to a ventilation system and the like are also well known. Examples showing various connecting means are: U.S. Patent No. 3,088,466 to Nichols; U.S. Patent No. 3,659,612 to Shiley, et al.; U.S. Patent No. 4,009,720 to Crandall, et al.; and U.S. Patent No. 4,315,545 to Crandall, et al., also assigned to Shiley. All of these patents show various means for interconnecting the inner cannula and the outer tracheostomy tube cannula by means of a coupling connector. It is common for all of these patents, that the coupling connection means to the ventilator or the like is integral with or connected to the removable inner cannula and that an additional connection is required between the outer tracheostomy tube cannula and the body of the inner cannula.

Tracheostomy tubes of this design have several disadvantages. First, they require an additional disconnection point between the outer and inner cannula which reduces the safety of the system. Such prior art

tracheostomy tube devices must have an air tight seal between the inner and outer cannulae and at the ventilator connecting means which is typically part of the inner cannula.

Second, the need exists in the art to improve the security of the respiratory system so that the accidental disconnection of the parts of the tracheostomy tube assembly can be prevented. At the present time there is no interconnecting system in the respiratory art that can provide high security for the connection of an inner cannula within respiratory circuit.

Third, the need has been emphasized for some time to provide a system which will only be disconnectable at the ventilator connecting means. The problem is discussed in a study by Arthur D. Little entitled: "Accidental Disconnection of Breathing Circuits". The current state of the art tracheostomy devices, by design and preferred embodiment, require an additional disconnection point which reduces the safety of the patient. The preferred embodiment of the present invention, proposes to overcome the above discussed disadvantages of the prior art.

According to the preferred embodiment of the present invention, the ventilator circuit is provided with a tracheostomy tube having a ventilator connection means integral to the outer tracheostomy tube cannula, and a removable inner cannula tube made separately from the outer cannula and placeable inside the outer cannula and the ventilator connection means. This design enhances the safety of the respiratory air delivery system. The removable inner cannula is safely placed inside the connector while the device is attached to various ventilator

connection means such as elbows, swivels, connectors, etc., minimizing the possibility of unintentional disconnection.

Summary of the Present Invention

The purpose of this invention is to provide a tracheostomy tube with a removable inner cannula adapted for placement inside the ventilation delivery system which will enhance the safety of the connection of the tracheostomy tube by eliminating a possible disconnection point between the inner and outer cannulae at the connector site.

Another purpose of the present invention is to provide a means for facilitating removal of an inner cannula from the ventilator coupling connector member of the outer tracheostomy cannula.

Still another purpose of this invention is to provide a system allowing easy and dependable interconnecting of the inner cannula within the ventilator coupling connector body without the necessity for using a sealing means between the outer cannula, the inner cannula and/or the ventilator connector member.

Yet another important purpose of the present invention is to provide the device which would accomplish the above functions with a simple and inexpensive structure.

To this end, the present preferred embodiment of the removable inner cannula is placed inside the air delivery path of the tracheostomy tube with locking means at its proximal end adapted for snap-fit interconnection into the tracheostomy tube ventilator connector member. The locking means are also provided with a grasping means for facilitating a withdrawal of the inner cannula from the connector member.

Brief Description of the Drawings

The preferred embodiment of the present invention device will now be described in more detail with reference being made to the drawings in which:

Fig. 1 shows a perspective view of the removable inner cannula according to the present invention inserted into the connector member.

Fig. 2 shows the embodiment shown in Fig. 1 with removable inner cannula withdrawn from the connector.

Fig. 3 shows cross-section taken along lines 3' of Fig. 1.

Detailed Description of the Preferred Embodiment

Referring first to Fig. 2 the inner cannula tube 10 is shown withdrawn from the connector member 8. As clearly appears from Fig. 2 the inner cannula 10 is made as a part separate from the connector member 8. The inner cannula has a first end 3 and a second end 5. The first end 3 is insertable through the opening 17 in the circular connector member 8 into an outer tube (not shown). The outer tube of the tracheal system can be permanently connected to the connector member or made integral with the connector. The inner cannula tube 10 includes a ribbed-grooved member 14 provided at its second end 5. Member 14 is inserted onto the outer wall of the tube 10 and includes a plurality of ring-like ribs 20 forming grooves 22 therebetween. The exterior ring-like rib 16 is partially cut around the major portion of its circumference.

As clearly shown in Fig. 2 the exterior ring 16 forms a ring-pull feature constituting a grasping means. The ring 16

can be folded integrally with the remaining portion of the member 14 and can be easily grasped with the fingers to facilitate removal of the inner cannula from the connector. As shown in Fig. 1 the grasping means of the inner cannula member is extending beyond the connector member 8 when the inner cannula 10 is fitted into the connector member and is easily reachable for removal of the inner cannula. At the same time, the ring-pull feature takes a minimum of space inside the coupling connector. The ribbed-grooved member 14 in the preferred embodiment is made from a flexible plastic polymeric material.

The removable inner cannula is adapted for interlocking into the connector body through the ribbed-grooved member 14. As better shown in Fig. 3 the connector 8 at its first end 11 includes locking means 15 on the interior wall of the connector member 8 for interacting with the member 14 of the inner cannula 8. This locking means includes at least a pair of circular ribs 17 forming a groove 19 therebetween and adapted for snap-fit connection with corresponding ribbed-grooved member 14. A presence of the definite snap-fit provides simple but dependable indication that the inner cannula device is in place within a connector member.

Placement of the removable inner cannula inside the connector member within the air delivery system is very advantageous. It reduces the possibility of accidental disconnection between inner and outer cannulae. When the respirator connection is made to the tracheostomy device, the plastic deformation of the connector member provides additional clamping force holding the inner cannula in place.

The tracheostomy assembly according to the present invention allows therefore to dispense with any conventional sealing

means necessary for known tracheostomy tubes having removable inner cannula.

The degree of safety of the present invention tracheostomy device is superior in comparison with prior art devices since the coupling connector 8 is always available for connection to a respirator circuit with or without inner cannula 10 being placed inside the outer tube.

The inner cannula of the present invention is described in the preferred embodiment in connection with tracheostomy assemblies using 15 mm and 22 mm coupling connector. However, the locking and grasping features described here in connection with the inner cannula can be used in many other applications. It can for example be utilized with replaceable filter systems attached to the ring pull feature and bacterial filters, moisture devices, and any type of device which could utilize the fold out ring for facilitation of its removal from an internal snap-fit or tempered locking device.

The connector 8 used with the removable inner cannula 10 is provided with a flange 2 which is made of a flexible material and attached to the opposite end 13 of the connector 8 with the pair of flexible pivot webs 6 molded to both the connector 8 and the flange 2. The webs 6 increase the flexibility of the flange 2 and provide for better comfort of the patient without the possibility of disconnection between the flange member 2 and the connector 8. The flange 2 can be made as a single piece molded flange including the webs 6.

In the preferred embodiment, the connector member 8 is designed as a 7° offset which lowers the position of the attaching apparatus from the upper neck and chin area. Two

tape slots 4 are provided in the flange member 2. The tape slots 4 are of a size sufficient to allow a full size half inch type tape to be easily threaded through the flange. The slots 4 will provide a high degree of flexibility to the system as well as guard against abrasion of the tape on the neck area. The provision of two flexible webs 6 and a large opening between the connector and the flange walls allows significantly larger open area around the stoma site and provide full view of the stoma for proper maintenance.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A removable cannula system comprising:

an outer cannula having a first and second end;

an inner cannula having a first and second end, said inner cannula being interconnectable inside said outer cannula at said second end;

first locking means disposed inside said outer cannula at said second end and second locking means disposed at said second end of said inner cannula for interconnecting said inner cannula inside said outer cannula; and,

grasping means for facilitating withdrawal of said inner cannula from said outer cannula, said grasping means including an annular ring with a hinge means connecting said annular ring to said inner cannula, said annular ring being alignable with an opening of said outer cannula at said second end and easily accessible to the fingers to be unfolded for pulling said inner cannula from said outer cannula.

2. A removable cannula system as claimed in claim 1 wherein said second locking means includes a plurality of ribbed-grooved members on said inner cannula and said first locking means includes at least a pair of corresponding ribs forming a groove therebetween on an inner wall of said outer cannula adapted for snap-fit interconnection with at least one of said ribbed-grooved members of said second locking means.

3. A removable inner cannula system as claimed in claim 2 wherein said hinge means connects said annular ring to said second locking means.

4. A tracheostomy tube comprising:

an outer cannula having a first and second end;

a tubular connector member integral with said outer cannula at said second end;

a removable inner cannula removably disposed inside said outer cannula, said inner cannula having a first and second end, said inner cannula being interlockable inside said connector member at said second end;

first locking means disposed inside said tubular connector member and second locking means disposed at said second end of said inner cannula for interconnecting said inner cannula inside said connector member; and

grasping means for facilitating withdrawal of said inner cannula from said outer cannula, said grasping means including an annular ring with a hinge means connecting said annular ring to said inner cannula, said annular ring being alignable with an opening of said tubular connector member and easily accessible to the fingers to be unfolded for pulling said inner cannula from said outer cannula.

5. A tracheostomy tube as claimed in claim 4 wherein said second locking means includes a plurality of ribbed-grooved members on said inner cannula tube and said first locking means includes at least a pair of corresponding ribs forming a groove therebetween on an inner wall of said outer cannula adapted for snap-fit interconnection with at least one of said ribbed-grooved members of said second locking means.

6. A tracheostomy tube as claimed in claim 5 wherein a diameter of said annular ring substantially corresponds to the diameter of the ribs of said locking means.

7. A tracheostomy tube as claimed in claim 4 wherein a diameter of said annular ring substantially corresponds to the diameter of the ribs of said second locking means.

8. A removable cannula system according to claim 2, wherein a diameter of said annular ring substantially corresponds to the diameter of the ribs of said second locking means.

9. A removable cannula system being substantially as herein described with reference to the accompanying drawings.

10. A tracheostomy tube being substantially as herein described with reference to the accompanying drawings.

DATED this 6th day of September, 1990.

PORTEX, INC.

WATERMARK PATENT & TRADEMARK ATTORNEYS,
290 Burwood Road,
HAWTHORN. VIC. 3122
AUSTRALIA

SKP:KJB:jl(10.16)

17444/86

FIG 1

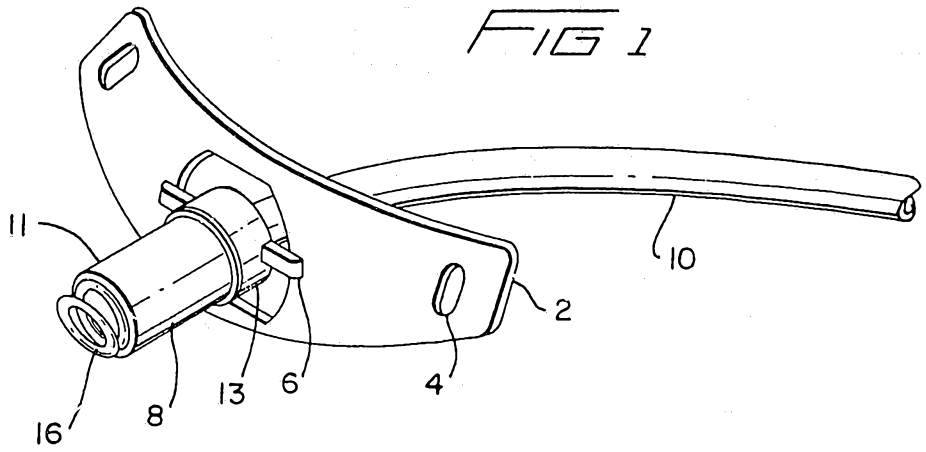
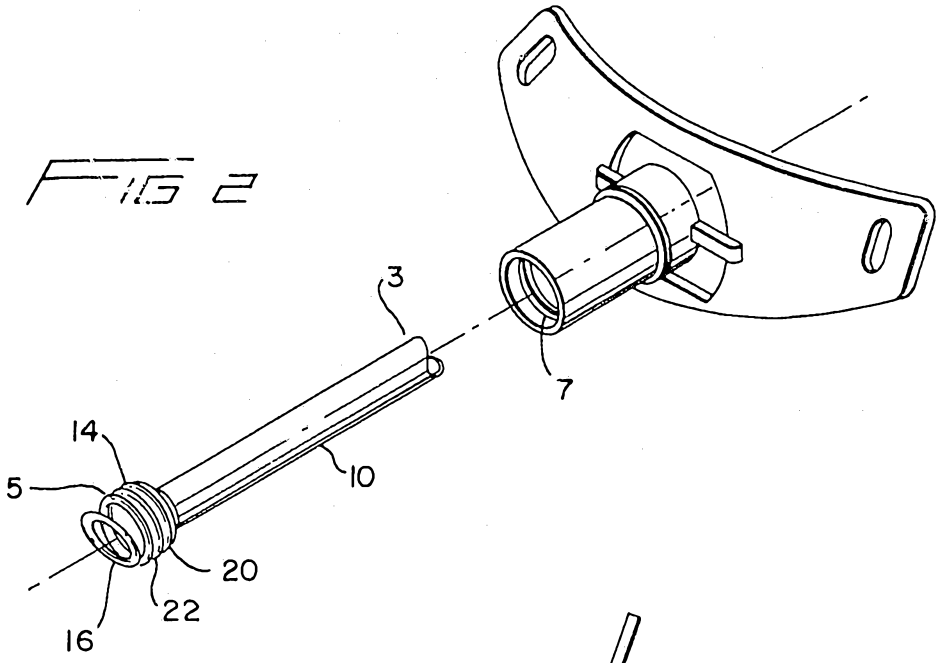


FIG 2



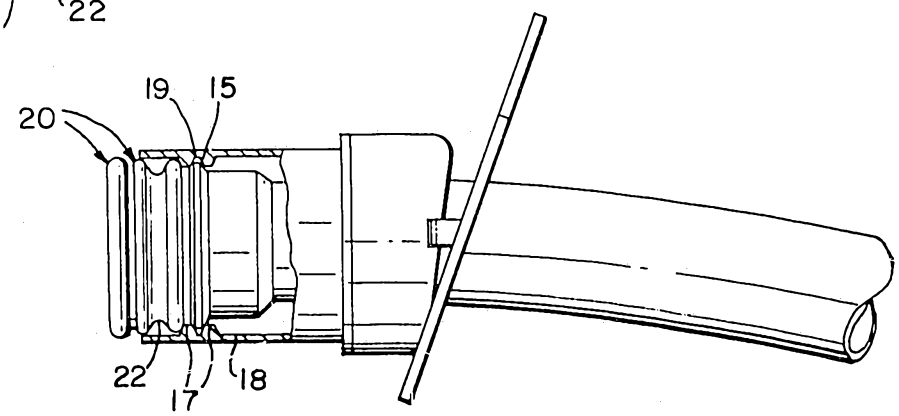


FIG 3