# **NATO STANDARD**

# AMedP-1.15

# COMPATIBILITY OF MEDICAL TUBING AND CONNECTORS IN THE FIELD

**Edition A Version 2** 

**MARCH 2021** 



# NORTH ATLANTIC TREATY ORGANIZATION

ALLIED MEDICAL PUBLICATION

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#### NATO LETTER OF PROMULGATION

30 March 2021

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R. TRABUCCHI FOR

Zoltán GULYÁS Brigadier General, HUNAF Director, NATO Standardization Office

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# **RECORD OF RESERVATIONS**

CHAPTER	RECORD OF RESERVATION BY NATIONS

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# **RECORD OF SPECIFIC RESERVATIONS**

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# TABLE OF CONTENTS

CHAPT	ER 1	INTRODUCTION	1-1
CHAPT	ER 2	GENERAL	2-1
CHAPT	ER 3	CONNECTIONS FOR TRACHEAL TUBES	3-1
CHAPT	ER 4	CONNECTIONS FOR THORACIC DRAINAGE TUBES	4-1
CHAPT	ER 5	CONNECTIONS IN SYSTEMS FOR INTRAVENOSUS	
		TRANSFUSION, INFUSION AND INJECTION OF FLUIDS,	
		DRUGS AND BLOOD	5-1
CHAPT	ER 6	CONNECTIONS IN SYSTEMS FOR COLLECTION OF	
		CORPORAL DEBRIS AND EXCRETA (NASOGASTRIC,	
		ASPIRATION AND URINARY PROBES)	6-1
6.1.	URINA	RY PROBES	6-1
6.2.	ASPIR	ATION PROBES	6-3
6.3.	NASOC	GASTRIC PROBES	6-6
ANNEX	Α	REFERENCES	A-1

#### CHAPTER 1 INTRODUCTION

Medical care in the field often requires the use of probes, catheters, drainage pipes and tracheal tubes. While one of the ends of these tubes is usually introduced into the body of the casualties, the other must be connected to external elements of the medical equipment (transfusion, infusion and injection systems, mechanical respirators, recipients and bags for collection of corporal debris and excreta...). The assembly between internal (introduced into the patient) and external (out of the patient) elements is achieved by means of different kinds of connectors.

The characteristics of these connectors are of great importance in the treatment of patients/casualties due to:

- The use of similar medical products with incompatible connectors can cause problems when medical units from different countries take part in the evacuation of casualties. These problems can cause the need to change the medical apparatus that have already been inserted into the patient, to even make it impossible to use these apparatus or medical equipment and the correct treatment of the patients in the worst case.
- The use of medical apparatus for different medical procedures using the same connectors can cause errors in their use or connection that can endanger the life of the patients.
- The use of different connectors in medical apparatus by different countries participating in the deployment, can lead to errors in the use of the apparatus inserted into patients that can endanger the life of the casualty.

Therefore, medical teams which participate in a multinational evacuation chain under NATO authority should have available compatible connections for medical tubes and catheters.

#### CHAPTER 2 DEFINITIONS

**Connector:** mechanical device that consists of one or two fittings and is designed to connect a tube for the transportation of liquids or gases.

**Male end**: end of a component intended to be connected with another component (female end) by being introduced into it. Therefore, its external surface takes part in the connection.

**Female end**: End of a component intended to be connected with another component (male end) which is introduced into it. Therefore, its internal surface takes part in the connection.

**Adaptor:** A connector designed to establish a functional continuity between components of differing types or those incompatible for each other.

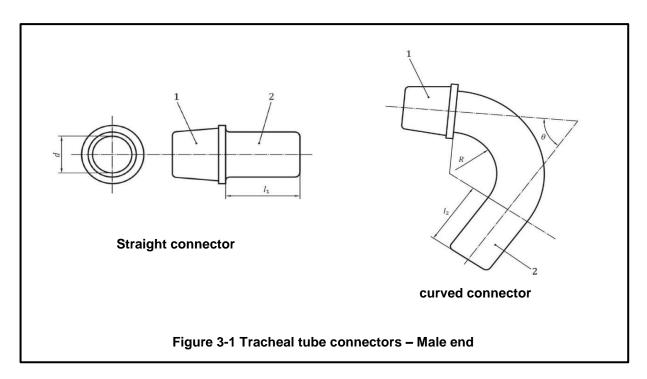
#### CHAPTER 3 CONNECTIONS FOR TRACHEAL TUBES

This group is composed by connectors of all the medical pipes made of semi-rigid materials, plastic or rubber which, introduced through the mouth or nasal cavity, will keep the air passage of the patient open and will allow connection to mechanical or manual respiratory systems. Among these components are the orotracheal, nasotracheal tubes or laryngeal masks. Other medical components that are connected to respiratory equipment such as tracheostomy tubes will also have these types of connectors.

These tubes will also have two parts, one that is introduced in the airway of the patient (patient end), and the other which will be outside the patient, where the breathing support systems are connected (outer end or apparatus end). In this exterior end is where the connector is found.

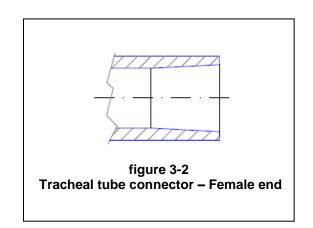
The connector at apparatus end will have the following characteristics: Connect the male lock fitting with the truncated-cone structure, of varying sizes depending on the internal diameter of the tube as shown in the table 3-1.

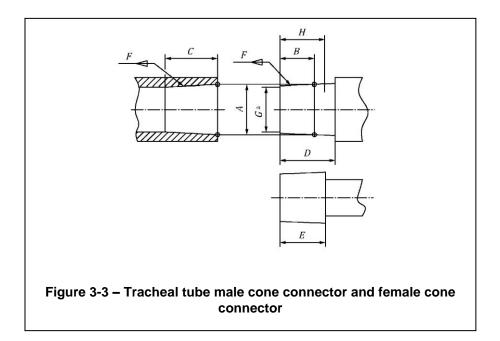
The characteristics of this connector are shown in the table 3-1 and figures 3-1 and 3-3. The size of each connector will in no case be inferior to that of the tracheal tube which is designed to be attached to, avoiding in this way any reduction in the flow of gas and reducing to a minimum the risk of fortuitous disconnections of the tube from the respiratory system and the respirator or the anesthetic respirator.



Designated size of the tracheal tube (Nominal inside diameter) mm	Inside size (d ± 0,15) mm	Minimum size <i>I</i> ı (straight connector)	Minimum size <i>l</i> <sub>2</sub> (curved connector)	
2,0	2,0	9	-	
2,5	2,5	9	-	
3,0	3,0	9	-	
3,5	3,5	11	-	
4,0	4,0	11	-	
4,5	4,5	12	-	
5,0	5,0	12	-	
5,5	5,5	13	10	
6,0	6,0	13	10	
6,5	6,5	16	10	
7,0	7,0	16	10	
7,5	7,5	16	10	
8,0	8,0	16	10	
8,5	8,5	16	10	
9,0	9,0	16	10	
9,5	9,5	16	10	
10,0	10,0	16	10	
10,5	10,5	16	10	
11,0	11,0	16	10	
Table 3-1: Tracheal tube connector - Range of sizes and dimension of the connector				

The apparatus end will be connected to a manual resuscitator or to a respiratory system of a respirator or an anesthetic respirator. This connection will be achieved by a female connector with an outer cylindrical form. The interior has a cone-shaped structure, with a maximum diameter, conicity and length of connector equal to those shown in the table 3-2 and figures 3-2 and 3-3 below.



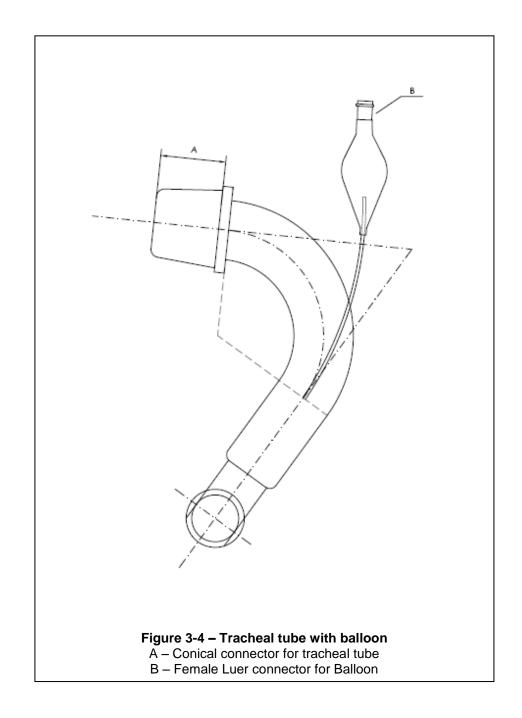


Connect or size mm	A mm	B mm	Minimum length of female cone C mm	Minimum length of male cone <i>E</i> mm	Conicity F	Minimum inside diameter of male connector <i>G</i> <i>mm</i>	Minimum length of inside diameter of male connector H mm
8,5	8,45 ± 0,04	6	6,4	8	1:19	6,25	6,0
11,5	11,50 ± 0,04	10	13,5	15	1:40	-	-
15	15,47 ± 0,04	10	16	14,5	1:40	-	-
22	22,37 ± 0,04	15	21	Figure 3	Figure 3	-	-
23	23,175 ± 0,02	13	18	15	1:36		
30	30,09 ± 0,05	14	18	14	1:20	27,0	12,0
Та	Table 3-2 – Tracheal tubes - Dimensions of the connectors of the tracheal tubes						

These characteristics are for connectors made of semi-rigid materials.

Some of these medical devices, the tracheal tube, also are equipped with systems for closing off the air flow, with the aim of isolating it totally, leaving the supply of gasses (oxygen, air and other medical gasses) only on the flow coming from the respirator (figure 3-4). The closing system is known as balloon, and it can be defined as an inflatable ball permanently attached around the tracheal tube, close to the patient end, that provides a hermetic seal between the tube and the trachea.

The balloon has an inflating tube, which is hermetically sealed at one end by means of a sealing component or inflation valve with a connector capable of accepting a male cone-shaped connector of 6% conicity (Luer) that meets the characteristics described in this document in CHAPTER 5.



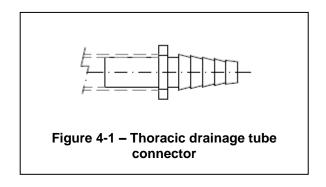
#### CHAPTER 4 CONNECTIONS FOR THORACIC DRAINAGE TUBES

The thoracic drainage tubes are medical devices that are used in thoracentesis procedures. This is the medical technique aimed at extracting an abnormal accumulation of liquid or air in the pleural cavity. The thorax drainage tubes will be catheters or needles which are inserted through the skin into the thorax cavity to reach the pleural cavity.

There are different types of catheters or thoracic tubes, which can be differentiated mainly by the technique used to insert the tube into the pleural cavity, and by the size: length (measured in centimeters) and diameter (measured in French) of the catheters used. However, all the thorax drainage tubes are connected to:

- Heimlich flutter valve
- Thorax drainage system with water seal

These medical devices would have for its fitting with the tube or thoracic catheter, flexible tubes with an inside diameter of a maximum of 8 mm. This makes that the thoracic drainage catheter must finished on a male conical connector with the external diameter in its finished end of  $4 \pm 0.4$  mm, and in its distal end of  $10 \pm 1$  mm (figure 4-1). This connector's surface can be smooth or it can have grooves. Being this preferably in order to contribute to a hermetic fitting.



There are some thoracic catheters, generally of small caliber for drainage of air from the pleural cavity (pneumothorax), which have at the end a female connector with a 6% Luer conicity. These catheters require an adapter with a male threaded Luer that allows it to be perfectly connected to the thorax catheter, and conical connector with the same features previously described which permits its connection to the drainage tube system.

As far as possible, thorax catheters should be used with connectors different from the Luer type, and in the case that they are used, this connector must be perfectly identified to avoid confusing it with an intravenous tube that can lead to introducing liquid in the pleural cavity, or the connection of a thorax drainage valve to an intravenous tube.

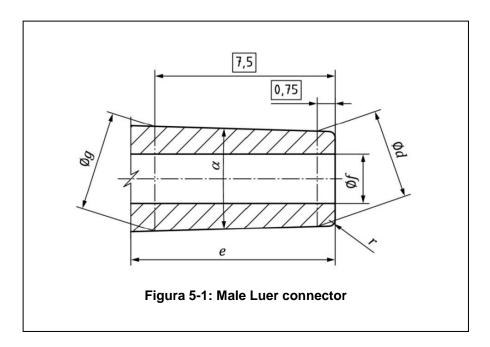
#### CHAPTER 5 CONNECTIONS IN SYSTEMS FOR INTRAVENOUS TRANSFUSION, INFUSION AND INJECTION OF FLUIDS, DRUGS AND BLOOD PRODUCTS

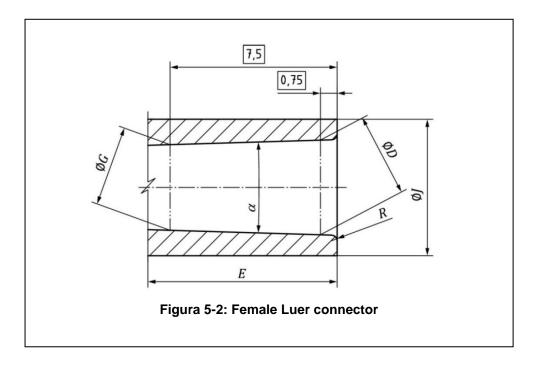
This type of connector is found in the following medical devices:

- Those used for accessing the vascular system, both arteries and veins.
- Those used injecting or extracting liquids under the skin, intramuscular, intraperitoneal or intraarticular.
- All those medical devices connected to the above mentioned used for the administration of fluids, transfusions, drugs...
- All those medical devices made to be connected to a syringe.

This connector features the fundamental characteristic of having a 6 % conicity fitting, also known as Luer conicity.

The fundamental features of this type of fitting are shown in the following figures, for the fitting of 6% male conicity (male Luer) in figure 5-1 and the female fitting of 6% conicity (female Luer) in figure 5-2.

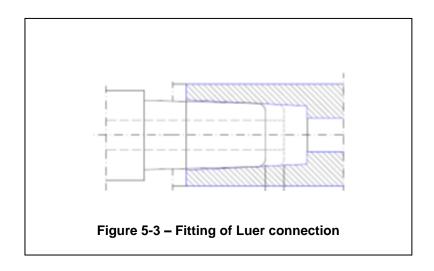




The dimensions of the fitting are shown in table 5-1:

SYMBOL		DESIGNATION	DIMENSIONS (mm)	
	Minimum	Minimum diameter of the lower part of the male conical fitting	3,970	
d	Maximum	Maximum diameter of the lower part of the male conical fitting	4,072	
D	Minimum	Minimum diameter of the conical female fitting opening	4,198	
U	Maximum	Maximum diameter of the conical female fitting opening	4,298	
~	Minimum	Minimum external diameter of the higher part of the male fitting, 7,500 mm from the other end.	4,376	
g	Maximum	Maximum external diameter of the higher part of the male fitting, 7,500 mm from the other end.	4,476	
Minimum		Minimum internal diameter of the higher part of the female fitting, 7,500 mm from the other end.	3,793	
G	Maximum	Maximum internal diameter of the higher part of the female fitting, 7,500 mm from the other end.	3,893	
e		Minimum length of the male conical fitting	7,500	
E		Minimum depth of female conical fitting	7,500	
Table 5-1 – Dimensions of conical fitting with 6% Luer conicity				

The fitting between the two connectors is done solely due to friction between their mating tapered surfaces when the male connector is introduced into the female connector. This connection must be hermetically sealed, allowing for the bi-directional flow of fluids through internal opening of both connectors. (figure 5-3).



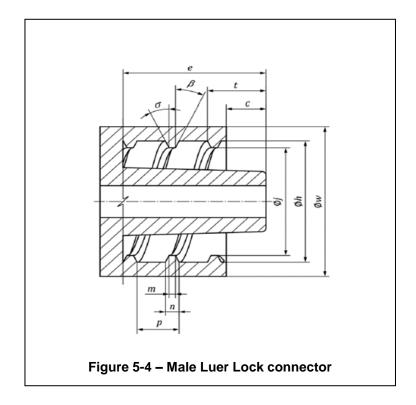
In the process of transferring fluids, at the point of fitting, it is possible for high pressure to build up. This, in some occasions, can lead to the disconnection of the male-female connection due to this increased pressure. This has been one of the reasons for the development of the Luer lock connector.

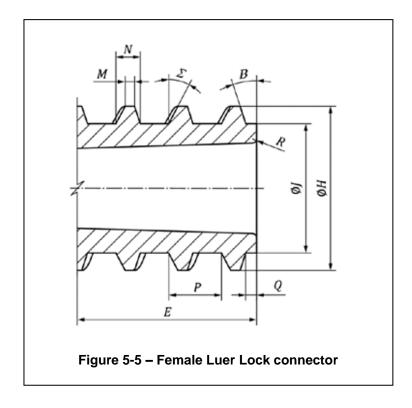
The Luer Lock fitting is able to increase the resistance to pressure caused by the transit of fluids by adding threading to the connector which gives greater durability to the male-female connection union.

This type of connection will maintain the same features of conicity of the male and female connectors, that is to say a conicity of 6%, where the fitting is made for the transfer of fluids. However, they also have additional connection elements:

- Female Luer: Has small tabs on the external surface.
- Male Luer: Has in the hollow cylindrical interior a threaded inner surface.

The characteristics and dimensions of these additional connecting parts are shown in figures 5-4 and 5-5 and in the table 5-2.





SYMBOL	DESCRIPTOR	DIMENSIONS (mm)		
SYMBOL	DESCRIPTOR	MINNIMUM	MAXÍMUM	
β	Angle of internal thread non-bearing surface against separation with the plane perpendicular to the axis of lock fitting	25°	57°	
σ	Angle of internal thread bearing surface against separation with the plane perpendicular to the axis of lock fitting	25°	30°	
С	Projection of nozzle from collar	2,100	2,573	
е	Length of male lock fitting	7,500	10,500	
E	Length of female lock fitting	7,500	10,500	
h	Root diameter of the thread of male lock fitting	7,900	8,100	
Н	Outside diameter of female lock fitting at crest of lugs or inside diameter of external thread. This diameter shall not be increased for a distance from the hub face of 5,5 mm	7,730	7,830	
j	Crest diameter of the thread of male lock fitting	6,800	7,200	
J	Outside diameter of female lock fitting at base of lugs or inside diameter of external thread. This diameter shall not be increased for a distance from the hub face of 5,5 mm	5,515	6,730	
т	Thread crest width of male lock fitting	0,300	0,674	
М	Lug crest width or thread crest width of female lock fitting with lugs or external thread	0,300	0,967	
n	Thread width of male lock fitting at root	0,627	1,000	
N	Width of base of lug (axial) or thread at base, of female lock fitting to be measured at a point corresponding to an outside diameter equal to $f$ (6,730 max)	0,533	1,200	
t	Distance from tip of male lock fitting to the bottom of first complete thread form of the internal thread	2,727	3,200	
Т	able 5-2 – Characteristics of the Luer lock o	onnection		

The connection of these two Luer connectors is done by means of the friction effect described above, to which is added the locking effect that is produced when the female connector is screwed into the male connector.

In this way a hermetic seal is achieved which is more resistant than a simple Luer. This type of connection must not be used in cases in which patients are being moved and in which abrupt movements could cause a pulling on the administration tubes for fluids that could lead to the catheter inserted in the patient being suddenly yanked out.

#### CHAPTER 6 CONNECTIONS IN SYSTEMS FOR COLLECTION OF CORPORAL DEBRIS AND EXCRETA (NASO-GASTIC, URINARY AND RECTAL PROBES

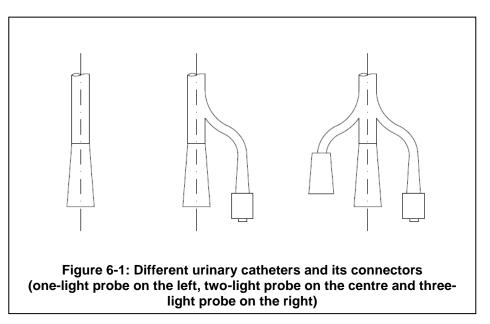
#### 6.1. URINARY PROBE CONNECTORS

Urinary probes, or urinary catheters, are tubular systems whose mission is to be inserted into the visceral cavity through the urethra in order to provide drainage and/or empty the bladder.

There are different models of urinary probes, which can be differentiated by the shape of the nozzle of the extremity that is inserted into the patient, the extremity orifice and lateral holes, length and width. We can also find probes with different types of connection systems or connectors at the external extremity.

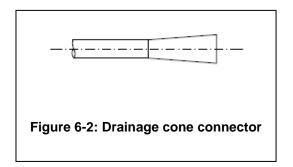
According to these connectors, we can differentiate three types of probes (figure 6-1):

- Single-light probe without balloon: They only have one drainage cone.
- Two-light probe with balloon:
  - Drainage cone.
  - Luer cone for inflating the ball which has the function of locking the probe in place to avoid accidental removal.
- Three-light probe with balloon:
  - Drainage cone.
  - Luer cone for inflating balloon.
  - Catheter cone for irrigation of liquids (solutions) for the purpose of washing or vesicle instillation.



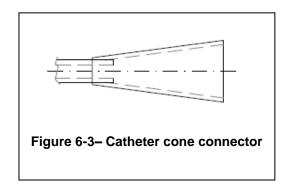
The dimensions of these cones are:

- Luer cone The inflation of the balloon is done with a syringe, so this connector will be a standard female connection to intravenous access described in CHAPTER 5.
- Drainage cone: Female connection in cone-shape with the following dimensions (figure 6-2):
  - At the nexus of the body of the probe it will have an internal diameter of 4 mm <u>+</u> 1 mm.
  - At its extremity (end) it will have a maximum internal diameter of 11 mm <u>+</u> 1 mm.
  - Maximum length 30 mm <u>+</u> 3 mm.



- Cone-shaped catheter: Female connector, cone-shaped with the following dimensions (figure 6-3):

- $\circ\,$  At its nexus with the body of the probe it will have a maximum diameter of 5  $\pm$  0.5 mm.
- $\circ$  At its extremity (end) it will have a maximum diameter of 11 ± 1 mm.
- The maximum length of the connector will be  $30 \pm 3$  mm.



The urine collection systems, which are connected to the probe in the drainage cone, must have a connector at the terminal extremity of the tube with the following characteristics:

- Male cone-shaped connector with the following dimensions:
  - $\circ$  At the end it will have an external diameter of 4mm ±1mm.
  - $\circ~$  At the far end, it will have a maximum external diameter of 14 mm  $\pm~$  1mm.
  - The maximum length of the connector will be 50  $\pm$  10 mm.

The medical devices used for the instillation of pharmacological solutions for vesicle cleansing will have the following connector, which is connected to a cone catheter:

- Male cone-shaped connector of the following dimensions.
  - $_{\odot}$  At its terminal extremity it will have an external diameter of 6  $\pm$  0.6 mm.
  - At its far end it will have a maximum external diameter of  $11 \pm 1.1$  mm.
  - The maximum length of the connector will be  $40 \pm 4$  mm.

#### 6.2. ASPIRATION PROBE

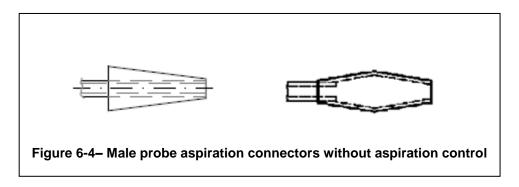
Aspiration probes are medical devices made of a flexible body with a uniform outer diameter, and with an extremity that is introduced into the patient which is known as the patient extremity. It has a terminal orifice and/or lateral holes, and the extremity of the apparatus is made to be connected to a vacuum system. Its function is to be introduced into the breathing airways to facilitate the aspiration of tracheobronchial secretions.

The connector of these medical devices will be the extremity of the probe apparatus. This extremity can be fitted with a male or female configuration, in the latter case needing an adaptor, which is to say, special connectors to establish a continuous functionality between components that are incompatible with each other.

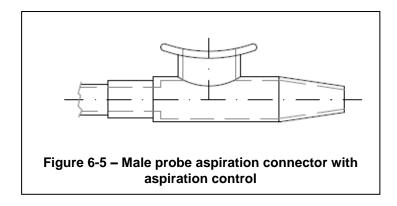
The different types of connectors for aspiration probes are:

A male connector without aspiration control (figure 6-4): Male cone-shaped connector which at its far end will have an external diameter of 7.5 ± 0.7 mm, and at its far end (joined with the probe tube) it will have an external diameter of 10 ± 1 mm. At all times the connector will maintain an internal light diameter equal or superior to the diameter of the probe connected to it.

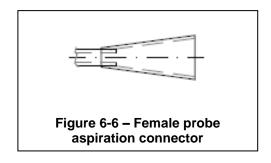
The surface of the connector can be smooth or have grooves. It is preferable that they have a grooved surface, given that this favors the hermetic seal with the aspiration tube.



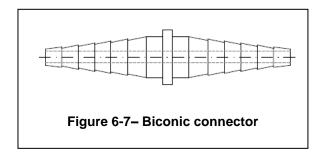
- Male connector with aspiration control (figure 6-5): It has the same characeristics and connection dimensions as the male connector, but it is made with a system to control the pressure of aspiration, allowing for it to be opened or closed and in this way control the apiration pressure.



Female connector (figure 6-6): Female cone-shaped connector, with a maximum internal diameter of 8 ± 0.8 mm at its far end and a minimum internal diameter that will depend on the diameter of the aspiration probe tube, given that at no time can it be smaller than the internal diameter of the probe it is connected to.



Aspiration probes with a male connector incorporated will be available, when possible, given that in this way there will be no need for an adaptor. In the case where a female connector is used, there must always be an appropriate adaptor available to connect it to an 8 mm diameter tube. This adaptor will consist of a biconic connector with a maximum external diameter of 8 mm and a minimum diameter of 6 mm, as shown in figure 6-7.



Either a male connector or the necessary adaptor is joined to an elastomeric tube with an interior diameter of 8 mm, which in turn is connected to a negative pressure system, providing the necessary vacuum to carry out its function.

Aspiration probe connectors (both male connectors with or without aspiration control as well as female connectors) are color coded to identify the size of the aspiration probe in accordance with the catalog of colors as shown in table 6-1.

Designated Size					
Charrière (French gauge equivalent)	Nominal outer diameter	Outer diameter tolerance	Minimum inside diameter	Color of the connector	
4	1,33	± 0,10	0,55	Purple	
4,5	1,5	± 0,10	0,70	Blue	
5	1,67	± 0,10	0,80	Grey	
6	2,0	± 0,10	1,0	Light green	
6,5	2,1	± 0,10	1,1	Yellowish green	
7	2,33	± 0,10	1,25	lvory	
7,5	2,5	± 0,10	1,45	Pink	
8	2,67	± 0,10	1,5	Light blue	
9	3,0	± 0,15	1,75	Turquoise	
10	3,33	± 0,15	2,0	Black	
12	4,0	± 0,15	2,45	White	
14	4,67	± 0,20	2,95	Green	
15	5,0	± 0,20	3,20	Brown	
16	5,33	± 0,20	3,40	Orange	
18	6,0	± 0,20	3,90	Red	
20	6,67	± 0,20	4,30	Yellow	
Table 6-1 – Color codes for the designated size of suction probes					

#### 6.3. NASOGASTRIC PROBES

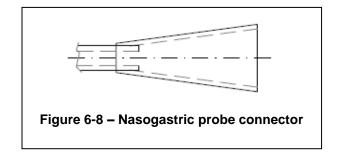
Nasogastric probes are medical devices that are made up of a flexible tube, having one or more lateral orifices and a connector, designed to be introduced (inserted) through the nose or the mouth, and by which nutrients or complete diets can be administered directly to the gastrointestinal tract, or used to extract gastrointestinal content by suction.

The nasogastric probe connector will be a female connector, with a cone-shaped structure which can be connected to either an enteral nutrition system or a joiner that allows for the connection of a nasogastric probe to an aspiration system.

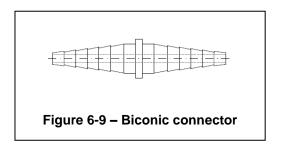
The following are the characteristics of the probe connector: Female connector with an internal diameter at its proximal end (inserted in the catheter tube) of  $6 \pm 0.6$  mm and an internal diameter at its distal end (or terminal) of  $7 \pm 0.7$  mm. The characteristics are described in figure 6-8.

This probe is connected to:

- Enteral nutrition administration systems: it is joined to the nasogastric probe by means of a male connector, with a cone-shaped structure and a minimum external end diameter of 6,4 mm. The minimum length of the connector is 12 mm.



- Adaptors for connection to vacuum systems. These are biconic joiners with a maximum external diameter of 8 mm and a minimum diameter of 6 mm as shown in figure 6-9.



Pediatric nasogastric probes will have a connector of a different size as described in this document. They will have a female connector of a smaller size. This connector must not be compatible with the conic 6% male Luer connector to avoid at all times possible administration errors.

#### ANNEX A REFERENCES

ISO 16142-1:2017 – Medical devices. Recognized essential principles of safety and performance of medical devices. Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards.

ISO 16142-2:2017 – Medical devices. Recognized essential principles of safety and performance of medical devices. Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards.

ISO 80369-1:2018 – Small bore connectors for liquids and gases in healthcare applications. Part 1: General requirements.

ISO 80369-7:2016 – Small-bore connectors for liquids and gases in healthcare applications. Part 7: Connectors for intravascular or hypodermic applications.

ISO 5356-1:2015 – Anaesthetic And respiratory equipment. Conical connectors. Part 1: Cones and sockets.

ISO 5361:2016 – Tracheal tubes and connectors.

ISO 20697:2018 – Sterile drainage catheter and accessory devices for single use.

UNE-EN 1615:2001 – Enteral feeding catheter and enteral giving sets for single use and their connectors. Design and testing.

ISO 20696:2018 – Sterile urethral catheter for single use.

ISO 8836:2014 – Suction catheters for use in the respiratory tract.

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