

ANTIMICROBIAL STOPCOCK MEDICAL CONNECTOR

BACKGROUND OF THE INVENTION

[0001] Infusion therapy generally involves the administration of a medication intravenously. When performing a typical infusion therapy, one or more infusion therapy device (e.g. tubing sets, catheters, etc.) are commonly used. In some instances, an infusion therapy device may include a stopcock medical connector to permit selective administration of a fluid through the infusion therapy device. The stopcock medical connector comprises a housing in which is rotatably seated a tap. The tap includes a fluid pathway that may be aligned (i.e., the open position) or misaligned (i.e., the closed position) within the housing to permit or prevent a fluid from passing through the housing. Thus, when administration of fluid is desired, the tap is rotated from the closed position to the open position to permit fluid to pass through the housing and into the patient via the infusion therapy device. Conversely, the tap is rotated to the closed position when it is desired to cease the administration of a fluid.

[0002] When in the closed position, fluid trapped within the fluid pathway of the stopcock medical connector remains stagnant and isolated from the remaining fluid within the infusion therapy device. Fluid within the infusion therapy device is also stagnant when in the closed position. These stagnant conditions are ideal for growth and colonization of microbes, which may lead to subsequent microbial infection when the medical connector is opened and the fluid is infused into the patient.

[0003] Thus, while methods and systems currently exist for selectively administering fluid to a patient via the use of a stopcock medical connector, challenges still exist. Accordingly, it would be an improvement in the art to augment or replace current techniques with the systems and methods discussed herein.

BRIEF SUMMARY OF THE INVENTION

[0004] The present invention relates to various antimicrobial stopcock medical connectors. More specifically, the present invention is related to systems and methods for providing an antimicrobial stopcock medical connector. The present invention is further related to a stopcock tap having fluid channels provided on portions of the outer surface of the stopcock tap, whereby fluid bypasses the stopcock through the fluid channels by flowing between the outer surface of the stopcock tap and the inner surface of the stopcock housing. Some embodiments further comprise an antimicrobial coating or insert that is provided in the one or more fluid channel, whereby fluid flowing through the fluid channels contacts the

antimicrobial coating or an antimicrobial agent that is eluted from the antimicrobial coating. Further still, some embodiments of the present invention comprise an antimicrobial groove that is positioned opposite the fluid channel, whereby when the stopcock is in an “off” position, the antimicrobial groove contacts fluid within a blocked port thereby preventing microbial growth therein.

[0005] Additional features and advantages of the invention will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the invention. The features and advantages of the invention may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. These and other features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] In order to describe the manner in which the above-recited and other advantages and features of the invention can be obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0007] Figure 1 shows a perspective, exploded view of an antimicrobial stopcock medical connector in accordance with a representative embodiment of the present invention.

[0008] Figure 2, shown in parts A and B, shows a cross-section view of an antimicrobial stopcock medical connector in an opened position in accordance with a representative embodiment of the present invention.

[0009] Figure 3, shown in parts A and B, shows a cross-section view of an antimicrobial stopcock medical connector in a closed position in accordance a representative embodiment of the present invention.

[0010] Figure 4, shown in parts A and B, shows a cross-section top view of an antimicrobial stopcock medical connector in open and closed positions in accordance with a representative embodiment of the present invention.

[0011] Figure 5, shown in parts A-E, shows cross-section views of an antimicrobial stopcock medical connector having three ports in open and closed configurations in accordance with representative embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0012] The present invention relates to various antimicrobial stopcock medical connectors. More specifically, the present invention is related to systems and methods for providing an antimicrobial stopcock medical connector. The present invention is further related to a stopcock tap having fluid channels provided on portions of the outer surface of the stopcock tap, whereby fluid bypasses the stopcock through the fluid channels by flowing between the outer surface of the stopcock tap and the inner surface of the stopcock housing. Some embodiments further comprise an antimicrobial coating or insert that is provided in the one or more fluid channel, whereby fluid flowing through the fluid channels contacts the antimicrobial coating or an antimicrobial agent that is eluted from the antimicrobial coating. Further still, some embodiments of the present invention comprise an antimicrobial groove that is positioned opposite the fluid channel, whereby when the stopcock is in an “off” position, the antimicrobial groove contacts fluid within a blocked port thereby preventing microbial growth therein.

[0013] Referring now to Figure 1, an exploded, perspective view of a stopcock medical connector 10 is shown. Stopcock medical connector 10 comprises a housing 20 generally having a tubular shape. Housing 20 comprises an opening or proximal end 22 that is sized to compatibly receive tap 30. In some instances, housing 20 comprises a side port of an intravenous device, such as a catheter adapter. Housing 20 further comprises a closed or distal end 24 that is located opposite opening 22, wherein housing 20 comprises a lumen 26 extending between proximal and distal ends 22 and 24. In some instances, distal end 24 further provides a seat surface that is configured to support tap 30 when seated within lumen 26.

[0014] In some instances, housing 20 further comprises one or more ports that are connected to housing 20 and in fluid communication with lumen 26. For example, in some embodiments housing 20 comprises an upstream port 40 and a downstream port 50. Upstream and downstream ports 40 and 50 each comprise a hollow interior, 42 and 52, respectively, that is in fluid communication with lumen 26. The free ends of ports 40 and 50 may be coupled to an intravenous device, such as a section of intravenous tubing, or a syringe. Fluid within upstream port 40 may pass into downstream port 50 by passing through lumen 26. Further, a fluid within lumen 26 may pass through either upstream or downstream ports 40 and 50, depending upon the desired direction of flow.

[0015] Stopcock tap 30 is configured to compatibly insert within lumen 26, whereby the base 32 of tap 30 is seated against the inner surface of distal end 24 when tap 30 is fully

inserted within housing 20. Tap 30 is rotatably seated within lumen 26. A fluid tight seal is further established between shaft 34 of tap 30 and lumen 26, whereby fluid within lumen 26 is prevented from exiting opening 22 when tap 30 is seated therein. In some instances, a hydrophobic lubricant, such as silicone grease, is inserted between shaft 34 and the inner surface of housing 20, thereby establishing the fluid tight seal. In other instances, proximal opening 22 comprises a mechanical seal, such as an o-ring, which established a fluid tight seal against shaft 34.

[0016] Shaft 34 comprises a circumference that is slightly less than the circumference of lumen 26. As such, shaft 34 may be inserted within lumen 26 with minimal tolerance. When inserted within lumen 26, the minimal tolerance between the outer surface of shaft 34 and the inner surface of lumen 26 prevents fluid from passing between upstream and downstream ports 40 and 50.

[0017] The outer surface of shaft 34 further comprises one or more fluid channels 36. In some instances, channels 36 comprise a groove forming a recess. Channels 36 comprise a length that is less than the circumference of shaft 34. In some instances, shaft 34 comprises a single channel 36 comprising a length that is less than half the circumference of shaft 34. In other instances, shaft 34 comprises two channels 36, each channel comprising a length that is less than one-third the circumference of shaft 34. Further, in some embodiments shaft 34 comprises three channels 36, each channel comprising a length that is less than one-fourth the circumference of shaft 34.

[0018] Shaft 34 may be rotated within lumen 26 to change the axial position of channels 36 within lumen 26. In some instances, shaft 34 is rotated within lumen 26 such that channels 36 are in simultaneous contact with the hollow interiors of upstream and downstream ports 40 and 50, as shown in Figures 2A, 2B and 4B. As such, channels 36 provide a fluid pathway between shaft 34 and the inner surface of lumen 26, thereby permitting fluid to flow between the hollow interiors 42 and 52. When shaft 34 is rotated within lumen 26 such that channels 36 are in contact with only one hollow interior, or no hollow interiors, fluid is prevented from bypassing shaft 34, as shown in Figures 3A-4A. Thus, selective flow of fluid 60 between upstream and downstream ports 40 and 50 may be achieved by rotating shaft 34 within lumen 26.

[0019] Referring now to Figures 4A and 4B, in some embodiments shaft 34 comprises a first fluid channel 36a and a second fluid channel 36b, each channel having a length that is less than one-half the circumference of shaft 34. Channels 36a and 36b further comprise an antimicrobial coating 70.

[0020] Antimicrobial coating 70 is an agent that kills microorganisms or inhibits their growth. Antimicrobial coating 70 may comprise any material or combination of materials that are compatible for intravenous use. In some instances, antimicrobial coating 70 comprises any type or form of antimicrobial material that is safe for use in accordance with the teachings of the present invention. For example, in some instances antimicrobial material 70 is selected from a group consisting of chlorhexidine diacetate, chlorhexidine gluconate, alexidine, silver sulfadiazine, silver acetate, silver citrate hydrate, cetrimide, cetyl pyridium chloride, benzalkonium chloride, o-phthalaldehyde, and silver element.

[0021] In some instances, antimicrobial coating 70 comprises an insoluble, cured coating. In other instance, antimicrobial coating 70 comprises a cured coating that is softened when exposed to fluid, thereby eluting a portion of the antimicrobial agent into the fluid. Further, in some instances antimicrobial coating 70 comprises a cured material forming a matrix in which an antimicrobial agent is loaded. Upon exposure to a fluid, the antimicrobial agent is slowly eluted from the matrix, thereby providing an antimicrobial zone of inhibition around the coated surfaces. Further still, in some instances antimicrobial coating 70 comprises a soluble coating that slowly dissolves upon prolonged exposure to a fluid.

[0022] In some instances, antimicrobial coating 70 comprises an antimicrobial insert that is inserted into fluid channels 36. The antimicrobial insert may comprise any compatible material. In some instances, the antimicrobial insert comprises a compatible polymer material that is coated with an antimicrobial agent or coating. In other instances, the antimicrobial insert comprises an antimicrobial material that configured for insertion within fluid channel 36. An antimicrobial material may include a polymer material that is prepared in combination with an antimicrobial agent, whereby the final material comprises antimicrobial properties. For example, in some instances the final material exhibits antimicrobial activity through direct contact with a fluid. In some instances, the antimicrobial insert comprises a metallic material, such as elemental silver.

[0023] In other instances, the final material elutes antimicrobial agent when contacted by a fluid, thereby providing a zone of inhibition surrounding the material. For example, in some embodiments antimicrobial material 70 comprises a UV cured, hydrophilic polymer material that forms a matrix comprising a plurality of microscopic interstices in which an antimicrobial agent is dispersed (not shown). Upon exposure to fluid 60, the polymer matrix is softened and penetrated by the fluid. The antimicrobial agent within the polymer matrix is eluted out of the matrix and into the fluid to form a zone of inhibition in proximity to the polymer matrix. Examples of suitable polymer materials are provided in United States Patent

Application Nos. 12/397,760, 11/829,010, 12/476,997, 12/490,235, and 12/831,880, each of which is incorporated herein in their entireties.

[0024] With specific reference to Figure 4A, shaft 34 is shown in an axial position where channels 36a and 36b are each in contact with only one hollow interior, i.e. 52 and 42, respectively, thereby preventing fluid 60 from bypassing shaft 34. The antimicrobial coating 70 in each fluid channel 36a and 36b is in direct contact with fluid 60, whereby preventing microbial colonization and/or growth in the stagnant fluid.

[0025] Upon rotation of shaft 34, channels 36a and 36b contact both upstream and downstream ports 40 and 50, thereby permitting fluid 60 to flow freely therebetween, as shown in Figure 4B. As fluid 60 passes through channels 36a and 36b, fluid 60 contacts antimicrobial coating 70, thereby preventing microbial growth and/or colonization on the coated surfaces. In some instances, antimicrobial agent within coating 70 is eluted from coating 70, thereby treating fluid 60 and providing a zone of inhibition around the coating channels 36.

[0026] Channels 36 may comprise any cross-section area to achieve a desired flow rate between upstream and downstream ports 40 and 50. In some instances, the combined cross-section areas of channels 36a and 36b are equal to the cross-section area of upstream or downstream ports 40 and 50. Where channels 36 comprise an antimicrobial coating 70, the combined cross-section area of the channel and the antimicrobial area are selected to ensure a desired rate of flow through device 10. Thus, channels 36 do not impede the rate of flow for device 10.

[0027] Referring now to Figures 5A-5E, housing 20 may further include a middle port 80 that is positioned between upstream and downstream ports 40 and 50 and comprises a hollow interior 82 that is in fluid communication with lumen 26. In some instances, shaft 34 comprises a single fluid channel 136 having a length that is greater than half the circumference of shaft 34. As such, shaft 34 may be axially aligned within lumen 26 of housing 20 such that fluid channel 136 is in simultaneous contact with hollow interiors 42, 52 and 82 of ports 40, 50 and 80, respectively, as shown in Figure 5A. In this position, fluid 60 is permitted to bypass shaft 34 and freely flow through the ports. Fluid channel 136 further comprises an antimicrobial coating 70 which is contacted by fluid 70 as fluid 70 passes through fluid pathway 136.

[0028] In some instances, shaft 34 is rotated counter-clockwise whereby fluid channel 136 is in fluid communication solely with upstream and middle ports 40 and 80, as shown in Figure 5B. Thus, fluid 60 is prevented from flowing into downstream port 50. Upon further

rotation of shaft 34 in a counter-clockwise direction, fluid channel 136 is placed in fluid communication solely with upstream port 40, as shown in Figure 5C. As such, fluid 60 is prevented from flowing into downstream and middle ports 50 and 80. Fluid 60 within upstream port 40 and fluid channel 136 is stopped, whereby fluid 60 remains in contact with antimicrobial coating 70 thereby preventing microbial colonization within lumen 26.

[0029] In some instances, as shaft 34 is further rotated in a counter-clockwise direction, fluid channel 136 is position such that fluid channel 136 is in fluid communication solely with upstream and downstream ports 40 and 50, as shown in Figure 5D. Thus, fluid 60 is permitted to flow freely between upstream and downstream ports 40 and 50, yet is prevented from flowing into middle port 80. Antimicrobial coating 70 is contacted by fluid 60 as fluid 60 passes through fluid channel 136.

[0030] Upon further rotation of shaft 34 in a counter-clockwise direction, fluid channel 136 is in fluid communication solely with downstream and middle ports 50 and 80, as shown in Figure 5E. Thus, fluid 60 may freely flow between downstream and middle ports 50 and 80, yet is prevented from flowing into upstream port 40. Fluid 60 flowing through fluid pathway 136 contacts antimicrobial coating 70, thereby preventing microbial growth and/or colonization, as discussed previously.

[0031] In some instances, shaft 34 further comprises an antimicrobial groove 90 that is positioned opposite fluid channel 136. Antimicrobial groove 90 comprises an antimicrobial coating in accordance with those materials discussed previously. Groove 90 is positioned on the outer surface of shaft 34 to align with one or more ports that are not in alignment or fluid communication with fluid channel 136. In other words, groove 90 is configured to be in fluid communication with one or more ports that are in an "off" position. As such, fluids within the respective ports are exposed to the antimicrobial material in groove 90, thereby preventing microbial growth or colonization within the ports while in the "off" position. As shown in Figure 5E, antimicrobial groove 90 is aligned and in contact with upstream port 40 when ports 50 and 80 are in contact with fluid channel 136. Thus, fluid 60 within all ports is exposed to antimicrobial agent 70 regardless of the "on" or "off" position of shaft 34 and the respective ports.

[0032] Some embodiments of the present invention further comprise a tap component for use with a stopcock medical connector. In some instances, a tap component is provided which comprises a first end having a handle, a second end opposite the first end, and an outer surface interposed therebetween. The outer surface further comprises a fluid channel forming a groove, as discussed above. When inserted within a stopcock medical connector,

the fluid channel forms a fluid pathway between the outer surface and a surface of the stopcock medical connector. For example, in some instances a fluid pathway is provided between the outer surface of the tap component and the inner surface of the stopcock medical connector housing. The fluid channel and fluid pathway thereby enable a fluid to bypass the tap component and flow through the stopcock medical connector.

[0033] The tap component may further include an antimicrobial agent applied to the fluid channel, wherein a fluid passing through the fluid channel contacts the antimicrobial material. The tap component may further include an antimicrobial groove formed in the outer surface and positioned such that the antimicrobial groove is in fluid communication with at least one port of the stopcock medical connector when in a closed position. The fluid channel may further comprise a length that is less than the circumference of the outer surface.

[0034] One having skill in the art will appreciate that the various other embodiments of the present invention may similarly be coated with an antimicrobial lubricant, thereby further adding a contact kill effect to the device. Various embodiments of the present invention may further be manufactured according to known methods and procedures. In some instances, an antimicrobial component is comprised of an antimicrobial material. In other instances, an antimicrobial component is extruded or molded of base polymer materials that have good bond strength to an antimicrobial material or agent, such as polycarbonate, copolyester, ABS, PVC, and polyurethane. The base polymer structure may be coated with an adhesive-based antimicrobial material, which may have elution characteristics. In some instances, the topology and dimensions of the base polymer structure are optimized for microbiology efficacy, lasting elution profiles, and assembly geometry constraints.

[0035] Various antimicrobial components of the instant invention may be casted or molded directly of antimicrobial material. In some instances, the antimicrobial component is casted in plastic and subsequently coated with an antimicrobial material. In some embodiments, an antimicrobial component is grown directly onto another component of the device. In other instances, various components of the device are joined together via an adhesive or epoxy. Antimicrobial components and coatings of the instant invention may be comprised of one or multiple antimicrobial agents in a polymer matrix. The polymer matrix may be adhesive-based, with a preference to acrylate- or cyanoacrylate-based adhesives for good bond strength and fast elution rates. Solvents may be added to increase bonding. Non-limiting examples of suitable antimicrobial material compositions are provided in United States Published Patent Application Nos. 2010/0137472, and 2010/0135949, each of which is incorporated herein by reference in their entireties.

[0036] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS

1. A stopcock medical connector device, comprising:

a housing having a proximal opening, a distal end, and an inner lumen extending therebetween, wherein the housing further comprises:

an upstream port having a hollow interior in fluid communication with the inner lumen;

a downstream port having a hollow interior in fluid communication with the inner lumen, wherein the downstream port is parallel to the upstream port; and

a middle port having a hollow interior in fluid communication with the inner lumen; and

a tap rotatably seated in the inner lumen of the housing and comprising a shaft having an outer surface comprising;

a fluid channel formed on the outer surface of the shaft, the fluid channel having a length greater than half a circumference of the shaft, the fluid channel providing a fluid pathway substantially free of flow restrictions between the hollow interior of the middle port and the hollow interior of the downstream port when the tap is rotated to a first position, the outer surface of tap preventing fluid communication between the downstream and upstream ports when the tap is rotated to the first position, and wherein when the tap is rotated to a second position, the fluid channel is in fluid communication with only one of the upstream port, the downstream port, and the middle port; and

an antimicrobial groove formed in the outer surface of the shaft and positioned such that the antimicrobial groove is in fluid communication with the upstream port when the tap is in the first position, the antimicrobial groove comprising an antimicrobial material in contact with a fluid within the upstream port when the tap is in the first position, wherein a length of the antimicrobial groove is less than a length of the fluid channel.

2. The device of claim 1, further comprising the antimicrobial material applied to the fluid channel, wherein a fluid passing through the fluid channel contacts the antimicrobial material.

3. The device of claim 1, wherein the antimicrobial material comprises at least one of a cured coating, a lubricant, a soluble coating, and an insoluble coating.

4. The device of claim 1, wherein at each point of rotation for the shaft within the inner lumen, the upstream, downstream, and middle ports are in contact with the antimicrobial material in at least one of the fluid channel and the antimicrobial groove.

5. The device of claim 1, wherein the fluid pathway extends between the shaft and an inner surface of the housing, and wherein the inner surface of the housing is interposed between at least two ports.

6. A method for manufacturing a stopcock medical connector, the method comprising steps for:
providing a housing having a proximal opening, a distal end, and an inner lumen
extending therebetween, the housing further comprising:

an upstream port having a hollow interior in fluid communication with the inner lumen;

a downstream port parallel to the upstream port, the downstream port having a hollow interior in fluid communication with the inner lumen; and

a middle port having a hollow interior in fluid communication with the inner lumen;

rotatably seating a tap in the inner lumen of the housing, the tap comprising a shaft having an outer surface; and

forming a fluid channel in the outer surface of the tap, the fluid channel providing a fluid pathway substantially free of flow restrictions between the hollow interior of the middle port and the hollow interior of the downstream port when the tap is rotated to a first position, the fluid channel having a length greater than half a circumference of the shaft, the outer surface of the tap preventing fluid communication between the downstream and upstream ports when the tap is rotated to the first position, and wherein when the tap is rotated to a second position, the fluid channel is in fluid communication with only one of the upstream port, the downstream port, and the middle port;

forming an antimicrobial groove formed in the outer surface of the shaft, wherein the antimicrobial groove is in fluid communication with the upstream port when the tap is in the first position, the antimicrobial groove comprising an antimicrobial material in contact with a fluid within the upstream port when the tap is in the first position, wherein a length of the antimicrobial groove is less than a length of the fluid channel.

7. The method of claim 6, further comprising a step for applying the antimicrobial material to the fluid channel, wherein a fluid passing through the fluid channel contacts the antimicrobial material.
8. The method of claim 6, wherein the antimicrobial material comprises at least one of a cured coating, a lubricant, a soluble coating, and an insoluble coating.
9. The method of claim 6, wherein at each point of rotation for the shaft within the inner lumen, the upstream, downstream and middle ports are in contact with the antimicrobial material in at least one of the fluid channels and the antimicrobial groove.
10. The device of claim 6, wherein the fluid channel defines a fluid pathway between the shaft and the inner surface of the housing, and wherein the inner surface of the housing is interposed between at least two ports.
11. A stopcock medical connector device, comprising:
- a housing having proximal opening, a distal end, and an inner lumen extending therebetween, the housing further comprising:
 - an upstream port having a hollow interior in fluid communication with the inner lumen;
 - a downstream port and having a hollow interior in fluid communication with the inner lumen;
 - a middle port having a hollow interior in fluid communication with the inner lumen;
 - a tap rotatably seated in the inner lumen of the housing and comprising a shaft having an outer surface comprising:
 - a fluid channel formed on the outer surface of the shaft, the fluid channel providing a fluid pathway between the downstream and middle ports and not the upstream port when the tap is rotated to a first position; and
 - an antimicrobial groove formed in the outer surface of the shaft and positioned such that the antimicrobial groove is in fluid communication with the upstream port the tap is in the first position, the antimicrobial groove comprising an antimicrobial material in contact with a fluid within the upstream port when the tap is in the first position;

wherein the outer surface of tap prevents fluid communication between the downstream and upstream ports when the tap is rotated to the first position;

wherein when the tap is rotated to a second position, the fluid channel is in fluid communication with only one of the upstream port, the middle port, and the downstream port,

wherein when the tap is rotated to a third position, fluid travels between the upstream port and the middle port via the fluid channel and between the upstream port and the downstream port via the fluid channel, wherein when the tap is rotated to the third position, the antimicrobial groove is not in fluid communication with the upstream port, the middle port, or the downstream port.

12. The device of claim 11, further comprising an additional antimicrobial material applied to the fluid channel, wherein a fluid passing through the fluid channel contacts the antimicrobial material.
13. The device of claim 11, wherein the antimicrobial material comprises at least one of a cured coating, a lubricant, a soluble coating, and an insoluble coating.
14. The device of claim 11, wherein at each point of rotation for the shaft within the inner lumen, the upstream, downstream and middle ports are in contact with the antimicrobial material in at least one of the fluid channel and the antimicrobial groove.
15. The device of claim 11, wherein the fluid channel defines a fluid pathway between the shaft and an inner surface of the housing, and wherein the inner surface of the housing is interposed between at least two ports.