

## RESEALABLE CONDUIT AND METHOD

## BACKGROUND

The present invention is directed to a resealable conduit and method for removing or adding fluid to a closed system. The fluid can be of any type.

Physiological fluid samples in containers need to be easily accessible without compromising the integrity of the sample. Closed systems such as stoppered physiological fluid sample tubes are accessed to remove one or more aliquots of the fluid. Alternately, fluid can be added to the sample tube, such as when a dilution is desired. Various diagnostic and therapeutic tests can be performed upon the aliquots. Physiological fluids such as, for example, blood or urine are frequently collected and stored in sample tubes closed by a rubber or elastomeric material stopper.

Typically, fluid samples are removed from a stoppered tube by removing the stopper, inserting a pipette stem into the fluid, aspirating fluid into the pipette and replacing the stopper. This access method can create aerosols and exposes sample fluid to the local environment. Aseptic conditions can thereby be violated. Biohazard can arise when this prior art fluid access method is used if the sample tube contains virulent or infectious organisms. These problems are compounded when the sample tube is reaccessed to remove further fluid samples.

A further problem is coring, which can occur when a hollow conduit is inserted through a rubber or like-material stopper. Coring is the removal of stopper material from the wall of the stopper as a hollow conduit is forced through the stopper. The cored material can enter the bore of the conduit thereby blocking it. Additionally, cored material can fall into the sample fluid when insertion of the conduit is complete, thereby contaminating the sample and rendering it unsuitable for analysis.

Needle tip conduits for piercing rubber septums or stoppers are known. These devices suffer from the disadvantages of coring, lack of a closure valve to prevent fluid backflow when tipped or inverted, high cost and inability to maintain essentially aseptic conditions.

Accordingly, there is a need for a low cost stored in closed sample tubes without coring and with maintenance of a high level of fluid asepsis. The device and method should permit repeatable access to such body fluids with minimal risk of creating aerosols, biohazard or contamination of either sample fluid or the sampling environment.

## SUMMARY

The present invention is directed to a low cost resealable conduit device and method which meets these needs. The resealable conduit can be inserted with little or no coring, through a rubber or like-material stopper of a fluid-containing sample tube. An elongated tubular member such as the stem of a pipette is inserted through the conduit to aspirate fluid. Alternately, fluid can be added by the pipette. The resealable conduit has closure means to prevent fluid backflow during normal handling, has re-entrant capability, is disposable, and minimizes risk of aerosol creation or contamination of a sample or the sampling environment.

A resealable conduit according to the present invention has guide means, puncturing means, and valve means. The guide means receives and guides the leading

end of an elongated tubular member, such as a pipette stem, into the bore of the conduit. The guide means has a mouth into which the tubular member can be removably inserted. The puncturing means is used for puncturing a rubber or like-material stopper so that the conduit can be inserted through the stopper. The normally closed valve means is disposed in the conduit bore.

The mouth of the guide means can have a cross-sectional shape that is, for example, square, rectangular, circular, or elliptical. Preferably, the mouth of the guide means is circular or elliptical and the guide means is funnel-shaped.

The puncturing means preferably has a beveled tip to assist passage of the conduit through a stopper. The wall adjacent the leading edge of the bevel tip can be thickened for support. The leading edge can have a needle point or a flat puncturing surface. Alternately, the flat puncturing surface can be in the form of a blade surface extension.

Preferably, the valve means is a "duck bill" valve because such valves are easy to make, inexpensive and effectively provide the desired one way mechanical access while preventing fluid backflow.

The guide and puncturing means can be formed as parts of an integral conduit body or they can be formed separately and assembled. To provide structural support, a reinforcing rib can run vertically along the exterior of the conduit.

A preferred method for removing fluid from a closed system includes the steps of: inserting the beveled tip of a resealable conduit through a closure member of the system; inserting an elongated tubular member through the conduit; aspirating fluid into the tubular member; and withdrawing the tubular member from the conduit. The conduit can then close under valve action. This method can also include the additional step of scoring the top of the closure member before inserting the beveled tip through closure member to help prevent coring. A preferred method for adding fluid to a closed system is the same as that just recited, except that instead of aspirating fluid, fluid is dispensed through the tubular member.

An apparatus within the scope of the present invention for removing fluid from or adding fluid to a closed system can include a resealable conduit, an elongated tubular member, such as a pipette, a closure member, such as a rubber stopper, and any combinations thereof.

## BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects, and advantages of the invention are illustrated by the following drawings.

FIG. 1 is an exploded perspective view of a pipette, resealable conduit and stoppered sample tube.

FIG. 2 is a vertical, cross-sectional view of the resealable conduit taken along line 2—2 of FIG. 1.

FIG. 3 is a top plan view taken along line 3—3 of FIG. 2.

FIG. 4 is an enlarged bottom view taken along line 4—4 of FIG. 2.

FIG. 5 is a fragmentary, vertical, side cross-sectional view taken along line 5—5 of FIG. 2.

FIG. 6 is a fragmentary, vertical, cross-sectional view illustrating initial piercing contact by the resealable conduit.

FIG. 7 is a vertical, cross-sectional view of the resealable conduit in use.