

K960456

**Summary of Safety and Effectiveness**  
**Denver® Paracentesis Needle (#60-1200)**  
**Denver® Paracentesis Needle with Drainage Line (60-1100)**  
**Denver® Paracentesis Tray (#60-1000)**

IDENTIFICATION OF SUBSTANTIALLY EQUIVALENT DEVICE(S)

The Denver® Paracentesis Needle, Paracentesis Needle with Drainage Line, and Paracentesis Tray are substantially equivalent in intended use to the Endovations, Inc. Paracentesis Tray (K874063). The Denver® and Endovations devices are similar in that they are both single-use, sterile devices used for draining fluid from the peritoneal cavity (abdominal paracentesis), both for diagnostic and therapeutic purposes. Both trays provide the primary components required to perform paracentesis. The two devices differ in that the Denver® needle has a metal cannula and a two-part, non-coring trocar (the inner rounded end tube extends beyond the outer sharp needle whenever the trocar is in an area of low resistance, such as when the abdominal cavity is entered). The Endovations needle has a plastic cannula and a single non-coring sharp needle trocar. In addition, the Endovations needle is only offered as part of a paracentesis tray, whereas the Denver® needle is also offered alone (Catalog No. 60-1200) and with a drainage line and connectors (Catalog No. 60-1100). Both the Denver® and Endovations needles have sealed housings that prevent leakage of air or fluid into or out of the lumen through which the trocar was placed. This seal also prevents reinsertion of the trocar in both needles. The drainage ports of both devices (a luer port with a sealing diaphragm in the Denver® needle; a three-way stopcock in the Endovations needle) also prevent passage of air or fluid in or out of the port until accessed.

The Denver® Paracentesis Needle, Paracentesis Needle with Drainage Line, and Paracentesis Tray are also substantially equivalent in intended use to the Tri-Med Specialties, Inc. Paracentesis Tray (K932652). The Denver® and Tri-Med devices are similar in that they are both single-use, sterile devices used for draining fluid from the peritoneal cavity, and both incorporate a metal drainage cannula. Both trays provide the primary components required to perform paracentesis. The two devices differ in that the Denver® needle has a two-part, non-coring trocar and the Tri-Med needle has a single non-coring sharp needle trocar. In addition, the Denver® needle has a sealed housing that prevents leakage into or out of the lumen through which the trocar was placed, and prevents reinsertion of the trocar. The Tri-Med needle has no seal in the housing; thus

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fluid leakage out of the needle can occur with the trocar either in place or removed. Similar to the Denver® needle, the Tri-Med needle is offered alone, with a drainage line, and as part of a complete paracentesis tray.

#### DEVICE DESCRIPTION:

The Denver® Paracentesis Needle is a sterile device, for single use only. It is not to be resterilized. Components in the fluid path are non-pyrogenic. The device consists of an inner two-part trocar, an outer drainage cannula, and a trocar/cannula housing. The inner two-part trocar is a rounded, closed end tube with side holes, coaxially housed within a sharp-beveled hollow needle and the outer drainage cannula. The outer drainage cannula has a beveled tip and distal side holes to facilitate drainage.

As the two-part trocar penetrates the abdominal wall, the blunt portion of the trocar is forced back within the shaft of the needle portion of the trocar, exposing the sharp-beveled needle. The trocar/cannula housing contains a red indicator which is visible when the sharp-beveled needle is exposed. When the needle encounters low resistance, such as when the abdominal cavity is entered, the blunt portion of the trocar automatically re-extends out beyond the sharp needle, thereby helping protect against inadvertent organ puncture. Once the blunt portion of the trocar re-extends beyond the needle, the red indicator is no longer visible. Proper position in an area of fluid may also be confirmed by attaching a syringe to the end of the device and attempting aspiration.

Once in the abdominal cavity, the two-part trocar is removed, leaving the outer drainage cannula and housing in place for the paracentesis procedure.

The Denver® Paracentesis Needle with Drainage Line is a sterile device intended for single use only. It is not to be resterilized. The product contains one Denver® Paracentesis Needle, one drainage tubing line, and connectors to allow attachment to wall suction or a vacuum bottle.

The Denver® Paracentesis Tray is a sterile device intended for single use only. It is not to be resterilized. The tray contains one Denver® Paracentesis Needle, one drainage tubing line, connectors to allow attachment to wall suction or a vacuum bottle, and the primary components needed for performing the paracentesis procedure.

## INTENDED USE

The Denver® Paracentesis Needle, Paracentesis Needle with Drainage Line, and Paracentesis Tray are indicated for use in removing fluid from the peritoneal cavity (abdominal paracentesis). They are intended to be used for both diagnostic and therapeutic abdominal paracentesis procedures.

## SCIENTIFIC LITERATURE

Published studies indicate that abdominal paracentesis is a safe and effective procedure.

## PERFORMANCE TESTING:

Drainage rates for Denver® Paracentesis Needles were compared to Tri-Med Caldwell 15 GA Paracentesis Needle/Cannulas (K932652). The results indicate that the two devices have a similar drainage performance.

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