

Important safety information

Indication for USE:

The **alfapump**[®] System is intended for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis. It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination.

Contraindications:

The **alfapump**[®] System is MRI unsafe. Hyperbaric oxygen therapy is contraindicated.

Warnings, Risks, and Precautions: Consider risks associated with implanting the **alfapump**[®] System including risk of peritoneal cavity infections, Coagulopathy, Small bladder capacity and/or obstructive uropathy. The following procedures or therapies could impact the **alfapump**[®] System function: Supersonic therapy and high-frequency heat therapy, Transcutaneous Electrical Nerve Stimulation (TENS), Lithotripsy, Defibrillation, Radiation therapy, Electrocautery, or use of other implantable medical devices and wearable devices.

Adverse Events:

In addition to procedure related risks the following Adverse Events may occur: pump pocket hematoma, skin erosion, infection, pump migration, catheter clogging or other catheter complications resulting in tissue damage or loss of or change in therapy, genito-urinary complications, reduced kidney function, hepatic encephalopathy, progression of liver disease, and other systemic effects.

P230044 PMA approval letter on file

U.S. Federal law restricts **alfapump**[®] System to sale by or on the order of a physician.

The **alfapump**[®] System is currently not approved in Canada.

DSR[®] therapy is still in development and is currently not approved in any country. The safety and effectiveness of DSR[®] therapy has not been established.