

JAN 17 1997

K963872

510(k) SUMMARY

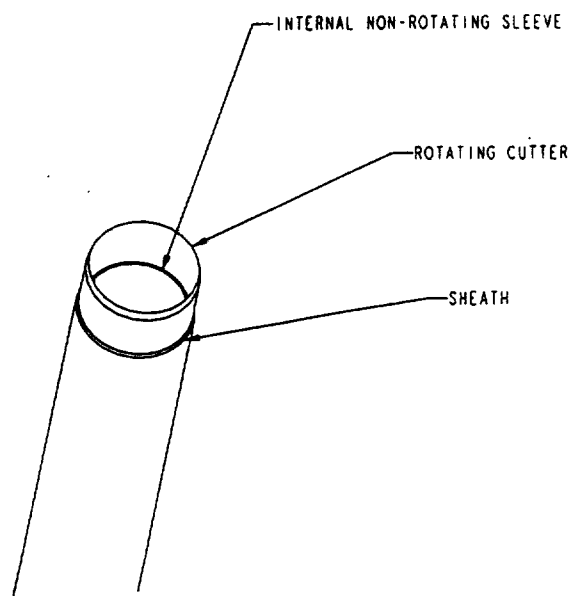
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The FemRx™ Morcellator System is virtually identical to the currently marketed Karl Storz STEINER™ Morcellator in terms of its tissue cutting and extraction mechanism. Both devices utilize a separate motor drive box and flexible drive cable to drive a rotating cutting blade, internal to a cylindrical housing, used to cut or core tissue as it is drawn up through the central lumen of the device by the use of standard forceps.

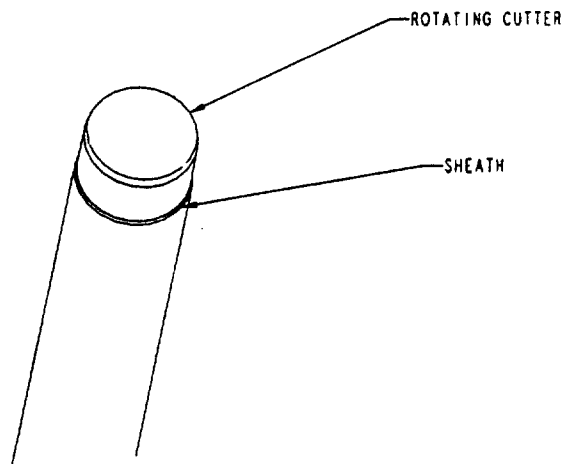
The principle difference between the FemRx™ Morcellator and the Storz device is that the FemRx device incorporates a fixed cylinder inside the rotating cutter (see figure below). The fixed (non rotating) cylinder located on the inside of the cutter is designed to reduce the torsional or rotational force applied to the cored tissue fragments as they are pulled up through the central lumen of the FemRx™ device.

The FemRx™ Morcellator System also differs from the Storz device in that it is disposable and utilizes the Motor Drive Unit (MDU) that has been previously cleared as part of the FemRx™ OPERA™ STAR™ and TURP™ STAR™ Hysteroscopic and Urological Resectoscopic Systems [510(k) numbers K954648 and K962506].

All tissue contacting materials are standard medical grade and non-toxic.



FemRx™ Morcellator



Storz STEINER™ Morcellator