

replacement component for the case. The lid is designed to eliminate the last degree of freedom for the instruments housed in the 2nd tier tray to prevent dislodgment from the brackets. The GentleThreads dilator is comprised of stainless steel and is attached via a Zimmer-Hudson quick-connect to a handle for use. The dilator is intended to enlarge a portal during an ACL reconstruction procedure to facilitate placement of an interference screw used for tibial fixation.

The SwitchCut Caddy is used with the Precision ACL Instrument Case and is designed to secure Sports Medicine Instruments targeted for various surgical procedures in the knee. The caddy is manufactured from stainless steel.

## 5.2 INDICATIONS / INTENDED USE

The devices that are identified and scheduled within Section 2.0 of this technical file are sterile and non-sterile instrumentation, intended for use in procedures involving Biomet Sports Medicine implantable components.

The devices included in this Technical File are hand-held, or hand-manipulated devices, intended to be used in ACL and PCL reconstruction surgeries and are intended for medical purposes to manipulate tissue, or for use with other devices in these surgeries.

## 5.3 STATEMENT ON CONTRAINDICATIONS

Contraindications can be found in IFU 01-50-1179, 01-50-1500, 01-50-1526, 01-50-1542, and 01-50-1528.