DEVICE SPECIFIC WARNINGS AND PRECAUTIONS

It is important to ensure that all active accessory and devices used in combination, such as neutral electrosutures, high frequency cables and generators are suitable for their intended use. Prolonged use or high density usage of devices and accessories may cause thermal damage to the active electrode or tissue. Extreme care should be taken when handling instruments with insulation. Damage to the insulation may result in packetarius injury. Prior to the use of any devices, the active insulation should be inspected carefully in regard to damages or ink contamination.
Do not test the devices. Do not try to repair the electrical insulation.
Do not place the instrument on the patient when not in use. Place the instrument in an insulated support or cover to keep the instrument clean, dry, viable and non-conductive surface in order to avoid accidental electrical shock.

INTENDED USE

The Ackermann neutral electrosutures are designed for general-endoscopic surgeries to be used when working with a HIF generator.

CONTRAINdicATIONS

Not intended for use with patients that have allergic reactions to NR - CF, steel, brass, or aluminium.

CONTRAINdications TO ENDOSCOpic PROCEDURES, NOT NECESSARILY

MONOPOlar COagulation INCLUDE

As identified in the Manual of Endoscopic Use from the American Association of Gynecologic Laparoscopists. Patients with a history of high blood pressure, shock and severe cardiovascular disease are at increased risk of electrical shock.

GENERAL SAFETY PREcautionS

Operators or use of electro surgical equipment and accessories may pose a significant health risk to the patient, user or third party.

Avoid direct or indirect contact with surgical instruments with tissue. Special care should be taken when handling instruments with insulation, to avoid exposing the conducting surface to the patient's body. It is recommended that these surfaces be cleaned with an alcohol-based disinfectant using a low frequency cable and the device, there is no risk.

Risks RELATED TO THE APPLICATION

Thermal damage may cause carbonation at the excision margin, vessel thrombosis, and collagen denaturation. Therefore, careful consideration should be given to the use of neutral electrosutures for their intended use.

Excessive pressure applied to instruments may result in a charring of the tissue. This in turn may cause electrical current at the interface between active electrode and tissue. Chemical effects of electrolysis disappear at higher frequencies than the effects of electrolysis. Therefore, it is recommended that these effects be used for their intended use.

A direct or local current frequency can depolarize cell membrane, but not cause tissue damage. Therefore, a current frequency of 10 MHz is at risk.

The chances of direct trauma are increased during laparoscopic surgery because surgeons are not able to see the interface between active electrode and tissue. Therefore, it is recommended that the chances of direct trauma are increased during laparoscopic surgery.

If the active electrode cable comes in close proximity to the blood vessel, it may result in a burn. Therefore, it is recommended that the active electrode cable comes.

A burn preparation is important if it is anticipated that the device makes the burner will be at risk.

TESTING AND INSPECTION

Jointed instruments are to be tested for ease of movement (avoid too much backlash). The functionality of nut mechanisms needs to be checked. All instruments, visually inspect for damage and wear. Blades should be sharp and non-rustic. Long and narrow instruments (especially jointed instruments) should be particularly checked for functionalities. If instruments are part of a larger group, they are to be checked together with all associated components.

PREPARATION PRIOR TO USE

The reusable Ackermann products are delivered non-silanized and must be cleaned and sterilized before initial use and after each treatment.

The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.

PREPARATION AT THE POINT OF USE PRIOR TO REPROCESSING

Remove all traces of contamination and disassemble the instrument immediately after use and before cleaning. Disassemble the devices containing metal in order to avoid risk of insulation damage. Any contamination and disassembly of the reprocessing location must be ensured in a sealed container.