

MPR Staples--Important Medical Information

DESCRIPTION

MPR Staples are available in different styles and sizes to provide a wide range of application options to satisfy physician preference and the unique demands of each particular case. All implantable components are designed for single use only.

PRECAUTIONS

1. Use extreme care in handling and storing implant components. Cutting, bending or scratching the surface of metal components can cause internal stresses, which significantly reduce the strength and fatigue resistance.
2. Certain special instruments are required to perform surgeries using staples. Review of the use and handling of these instruments is important. Single use devices should not be reused due to risks of breakage, failure or patient infection.
3. The patient should be informed that the staple may eventually be removed in a subsequent surgical procedure following evidence of healing.
Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

MPR Staples have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating or migration in the MR environment.

STERILIZATION

Components are supplied non-sterile and must be cleaned and sterilized prior to surgery. For non-sterile trauma implants, remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization.

DO NOT REUSE implant components or single use disposable instruments.

RECOMMENDED STEAM STERILIZATION CYCLE PARAMETERS

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes and a minimum vacuum drying time of 30 minutes.
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 minutes and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle (Reusable instruments only): Exposure temperature: 132°C (270°F) for 10 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.



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