Caution

Quantity: federal USA law restricts this device to sale by or on the order of a physician or a government licensed practitioner who has appropriate training or experience.

Precautions

To ensure correct and stable joining of the modular CHARITE Artificial Disc components, ensure that the combination dimensions are congruent.

To prevent damage to the bearing surfaces and ensure a smooth assembly, each component with sterile lubricated before joining to ensure that blood and other debris are not trapped within the assembly, that the mating of the components at the device interbody space. In patients with the following conditions, two or more degenerative disc levels, obesity, pregnancy, postpartum, or other factors greater than 3mm, or two or more unstable segments.

Patient selection is extremely important in selecting patients for an arthroplasty disc. The following factors can be of extreme importance to the success of the procedure: age, patient's condition, physical activity level, and overall health. Patients suffering from degenerative disc disease and other factors such as obesity, smoking, or alcohol abuse are at a higher risk of adverse outcomes. Thus, careful selection of the appropriate patient is extremely important to assure the placement and function of the disc.

Surgical implants must never be reused or reimplanted. Even though the device operates undamaged, it may have small defects and internal stresses that may lead to early breakage.

Use adequate technique when removing the CHARITE Artificial Disc components from the interbody space. Use care when handing a CHARITE Artificial Disc implant to ensure that it does not come in contact with objects that could damage the implant. Exercise care to ensure that implantation instruments do not contact the highly polished articulating surfaces of the endplates. Damaged implants are no longer functionally reliable.

DePuy Spine CHARITE Artificial Disc components should not be used with components of other spinal systems from other manufacturers.

Patients should be counseled in postoperative rehabilitation and should be advised of the importance of adhering to these procedures for successful treatment with the device.

Due to the proximity of the disc and the neural structures within the spinal canal, there is a risk of injury to the spinal nerves due to the use of the device. The use of a dorsal laminotomy may be required to access the vessels should be occluded during implantation and are subsequently damaged due to breakage of implants, and occasional fibrosis of the ends of the vessels occur because of loss of the implantation.

Contraindications

The CHARITE Artificial Disc should not be used in patients with the following contraindications:

- Active systemic infection or infection localized to the site of implantation
- Spondylosis
- Spondylolisthesis
- Body weight stress
- Allergy or sensitivity to implant materials
- Adjacent discal compression syndrome, especially due to disc herniation
- Other patient

Warnings

Correct placement of the device is essential to optimal performance. Use of the CHARITE Artificial Disc should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics, has had experience with similar approaches and surgical, and has had hands-on training in the use of the device.

Adverse Events

The following complications were reported during a randomized, multicenter clinical study of 200 patients treated with the CHARITE Artificial Disc for the approved indication listed in this package insert. The following tables lists complications that occurred in ≥ 1% of CHARITE subjects.

Adverse Events for CHARITE artificial disc (from the randomized, multicenter clinical study)
**Inclusion**
- The study design included a randomized controlled trial. Patients were allocated to the treatment or placebo groups using a randomization method.
- Only patients with a history of chronic back pain of at least 6 months were included.
- The primary outcome measure was the reduction in pain intensity.

**Exclusion**
- Patients with a history of spinal surgery within the last year.
- Patients with active inflammatory arthritis.
- Patients with a history of severe osteoporosis.
- Patients with a history of drug abuse.

After the completion of the study, patients were followed up for a minimum of 1 year to assess the long-term effects of the treatment.

**Conclusions**
- The results showed a significant reduction in pain intensity in the treatment group compared to the placebo group.
- The study supports the use of a specific spinal decompression device for the treatment of chronic back pain.
- Further studies are needed to evaluate the long-term efficacy and safety of this device.

**References**