

Indication

The InSpace™ Implant is intended for the treatment of patients with MRCTs for patients 65 years of age and older whose clinical conditions would benefit from treatment with a shorter surgical time compared to other surgical treatment options.

Contraindications

The InSpace™ Implant should not be used if you have the following conditions:

- Known allergy to the InSpace™ Implant material
- Active infection or tissue death in the shoulder area

The InSpace™ Implant is for adult patients only (65 years of age and older) and should not be used in children.

Warnings

The following Warnings are provided based on data collected in the US Pivotal Clinical Study. Please refer to the *safety information* below within “*How was the US Pivotal Clinical Study Performed?*” for further information on safety of the InSpace™ Implant.

- There is evidence of increased risk of total adverse events of the affected shoulder compared to a partial rotator cuff repair, which were reported to be mostly mild to moderate in severity. Please note that complications reported by InSpace™ and Partial Repair patients were reviewed by a group of experts in shoulder surgery, and it was determined that none were related to the treatment devices (i.e., the InSpace™ Implant or devices used for Partial Repair).
- There is evidence of increased adverse events associated with a serious risk of the index shoulder which includes both medical and surgical treatments.
- The InSpace™ Implant is not fixed in place and may change position in the shoulder space. Movement out of the subacromial space and/or deflation of the InSpace Implant was observed in magnetic resonance imaging (MRI) 6 weeks post-operatively in up to half of patients. In these cases, it should be noted that no re-operations were required to remove the InSpace™ Implant.

The risks and benefits of the InSpace™ Implant in patients with the following conditions should be carefully considered:

- Severe arthritis in the shoulder or full thickness cartilage loss
- Deltoid muscle defect or deltoid muscle paralysis
- Evidence that the shoulder is very unstable

- Missing or non-intact ligaments in the shoulder
- Known loss of sensation
- Major medical conditions such as blood clotting disorders, conditions that suppress the immune system or any other conditions that may compromise healing
- Safety and effectiveness of InSpace™ Implant use in patients below age sixty-five (65) has not been established
- Safety and effectiveness of InSpace™ Implant use in pregnant or nursing mothers has not been evaluated.

Precautions

It is important to follow your surgeon's advice regarding after surgery care (for example, physical therapy) as well as which immediate activities you may or may not perform after receiving the InSpace™ Implant. Not following this advice may cause complications with the InSpace™ Implant. Some complications may require you to have additional surgery.