English

Instructions for use

ACIS® ProTi 360°™ INTERBODY SYSTEM

ACIS® ProTi 360°™ HL INTERBODY SYSTEM

CONCORDE™ ProTi 360°™ INTERBODY SYSTEM

T-PAL™ ProTi 360°™ INTERBODY SYSTEM

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DePuy Synthes
COMPANIES OF Johnson & Johnson

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

DESCRIPTION OF THE MEDICAL DEVICE

The implants are:

- The DePuy Synthes Spine ProTi 360°™ Interbody Spacer is a Polyetheretherketone with a titanium plasma spray per ASTM F1580.
- The teeth on the superior and inferior ends resist expulsion in all directions.
- The device is open in the transverse plane to allow insertion of autograft into the device prior to placement.
- The tantalum markers used for this product are made to the voluntary standard ASTM F560.
- The radiolucent PEEK material allows visualization of the defect site on radiograph to assess bone growth.
- For all indications, this device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical, thoracic or lumbar spine (i.e. posterior pedicle screws and rod systems, anterior plate systems, and anterior screw and rod systems).

The DePuy Synthes Spine ProTi 360°™ Interbody devices are supplied sterile.

INDICATIONS FOR USE

Cervical System Indications:
The DePuy Synthes Spine ProTi 360°™ Cervical Interbody System is indicated at one or more levels of the cervical spine C2-T1 in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment.

The DePuy Synthes Spine ProTi 360°™ Cervical Interbody spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. These devices are intended to be used with supplemental fixation.

Lumbar System Indications:
The DePuy Synthes Spine ProTi 360°™ Interbody System is indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may also have had a previous non-fusion spinal surgery at the involved spinal level(s). Additionally, the DePuy Synthes Spine ProTi 360°™ Interbody System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. Patients should have six months of nonoperative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior, transforaminal, lateral or anterior approach using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.

MATERIAL

PEEK implants are manufactured from implant grade Polyetheretherketone (PEEK) per ASTM F2026. The DePuy Synthes Spine ProTi 360°™ interbody devices are constructed from Polyetheretherketone per ASTM F2026 and have a titanium plasma spray per ASTM F1580. Each implant contains tantalum markers per ASTM F560. The specialized instruments are made primarily of surgical grade stainless steel per ASTM F899.

HOW SUPPLIED

DePuy Synthes Spine ProTi 360°™ Interbody Systems are delivered **sterile** as specified by the packaging. All sterile implants are gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not resterilize.

DePuy Synthes Spine instruments are provided **non-sterile** and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

CONTRAINDICATIONS

The operation should not be carried out against the following contraindications:

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

WARNINGS AND POTENTIAL RISKS

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. All instruments must be cleaned and sterilized prior to surgery.
4. As with all orthopaedic implants, DePuy Synthes Spine Interbody Systems should never be reused under any circumstances.
5. The DePuy Synthes Spine Interbody System should never be used with dissimilar materials.
6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

PRECAUTIONS

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Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the contraindications section should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. All instruments should be cleaned and sterilized before use.

Intraoperative:

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions.
3. Autograft may be placed in the area to be fused.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the healing process.
4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the DePuy Synthes Spine Interbody Systems device components should ever be reused under any circumstances.

POSSIBLE ADVERSE EFFECTS

1. Bending, loosening or fracture of the implants or instruments;
2. Loss of fixation;
3. Sensitivity to a metallic foreign body, including possible tumor formation;
4. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
5. Nonunion or delayed union;
6. Infection;
7. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
8. Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
9. Pain or discomfort;
10. Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra);
11. Hemorrhage of blood vessels and/or hematomas;
12. Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height;
13. Bursitis;
14. Autograft donor site pain;
15. Inability to resume activities of normal daily living;
16. Reoperation;
17. Death.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

MAGNETIC RESONANCE (MR) COMPATIBILITY
Non-clinical testing has demonstrated the DePuy Synthes Spine ProTi 360°™ Interbody System Implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3.0T with quadrature driven coil
- Maximum spatial field gradient of 1900 gauss/cm (19.0 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the DePuy Synthes Spine ProTi 360°™ Interbody System Implants are expected to produce a maximum temperature rise of less than 6.1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by these devices extends approximately 12mm from the implant when imaged with a gradient echo pulse sequence and a 3.0T MRI system.

DIRECTIONS FOR USE

The operating surgeon draws up an operating plan that specifies and appropriately documents the following steps:
- Selection of the implant components and their dimensions
- Positioning of the implant components in the bone
- Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:
- All requisite implant components are ready to hand.
- Operating conditions are highly aseptic.
- The implantation instruments are cleaned and sterilized prior to use according to the procedures outlined in this document.
- The implantation instruments, including the special DePuy Synthes Spine Interbody System instruments, are complete and in working condition.
- The operating surgeon and operating team are aware of information concerning the operating technique and the range of implants and associated instruments; this information is complete and ready to hand.
- The operating surgeon is familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific publications by medical authors.
- The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.

The intervention has been explained to the patient, whose consent concerning the following information has been documented:
- In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads.
- The life-span of the implant depends on the patient's body weight.
- Corrective surgery may become necessary if the implant loosens.
- The patient must undergo regular check-ups of the implant components, performed by a physician.

Implanting the PEEK devices:
- Select the appropriate PEEK implant size and shape according to the indication, the preoperative planning, and the bone situation found intraoperatively.
- Correctly apply the preparation instruments (rasps, curettes and chisels) for preparing the implant bed, as well as the implantation instrument.
- To implant the DePuy Synthes Spine Interbody System Implants, use only the specialized DePuy Synthes Spine Interbody System instrumentation. Do not use implants or instruments from any other system or manufacturer.
- Apply appropriate care when inserting the implant.
- Check implant height and/or angle using the trial implants.

For complete instructions regarding the proper use and application of all DePuy Synthes Spine Interbody System Implants and instruments, please refer to the DePuy Synthes Spine Interbody Surgical Technique Manual (provided with the system).

CARE AND HANDLING

Sterilization:

For components provided Sterile, the sterilization method is noted on label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage prior to surgery. If sterile barrier has been broken, return component to DePuy Synthes Spine

If not specifically labeled **STERILE**, or if labeled NON-STERILE, components are supplied non-sterile and must be cleaned and sterilized prior to surgery.

Certain DePuy Synthes Spine PEEK and all ProTi 360°™ implants are provided sterile and cannot be resterilized.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact DePuy Synthes Spine Customer Service for return of removed implants.

LABEL SYMBOLS

SYMBOL	MEANING
Rx only	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
REF	Reference number
LOT	Lot number
MATL	Material
	Date of manufacture
	Expiration date
QTY	Quantity
STERILE R	Sterilized using irradiation
	Do not re-use
	Do not use if package is damaged
	Consult instructions for use
	Caution
DIST. BY	Distributed by
	Manufacturer
CE 2797	CE mark
EC REP	Authorized representative in the European Union
MD	Medical device
MR	Magnetic Resonance Conditional
UDI	Unique Device Identifier
	Double Sterile Barrier

CUSTOMER SERVICE

For further information regarding the DePuy Synthes Spine Interbody System or a copy of the DePuy Synthes Spine Interbody System Surgical Technique Manual, please contact DePuy Synthes Spine or your local DePuy Synthes Spine Distributor.