DePuy Synthes
COMPANIES OF Johnson & Johnson

ANTERIOR CERVICAL INTERBODY SPACER (ACIS®) PROTI 360°™ INTERBODY SYSTEM
ANTERIOR CERVICAL INTERBODY SPACER (ACIS®) PROTI 360°™ HL INTERBODY SYSTEM
CONCORDE™ PROTI 360°™ INTERBODY SYSTEM
T-PAL™ PROTI 360°™ INTERBODY SYSTEM
PACKAGE INSERT

DESCRIPTION OF THE MEDICAL DEVICE:

The implants are:

- The DePuy Synthes Spine ProTi 360°™ Interbody Spacer is a Polyetheretherketone with a Titanium plasma spray as described by 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 Spacers are interbody fusion devices 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.

DePuy Synthes Spine ProTi 360°™ 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 are 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 (6) weeks of non-operative 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.

INTENDED USE

The DePuy Synthes Spine ProTi 360°™ Interbody Systems are intended for use as intervertebral body fusion devices in skeletally mature patients.

Instrument Intended Use

Instruments are intended to be used to assist in the implantation and removal of the implants of each interbody system. Trials are used as a temporary placement guide prior to implant of interbody device and are used with the appropriate handle.

LIMITATIONS

With the exception of any limitations present in the Contraindications, Warnings and Potential Risks, and Precautions sections, there are no additional limitations when the DePuy Synthes Spine ProTi 360°™ Interbody Systems are used as intended.

TARGET PATIENT GROUP

The DePuy Synthes Spine ProTi 360°™ Interbody Systems are for patients who are skeletally mature. Additionally, patients should have at least six (6) weeks of non-operative treatment in the cervical and/or lumbar spine prior to surgery. The application of all implants is according to the judgement of the experienced spine surgeon with utilization at the appropriate anatomical locations as defined in the indications.

INTENDED USER

The DePuy Synthes Spine ProTi 360°™ Interbody Systems are intended for use by a physician only and should be used by experienced spine surgeons.

INTENDED USE ENVIRONMENT

The DePuy Synthes Spine ProTi 360°™ Interbody Systems are intended to be used in an operating room or surgical setting.

EXPECTED CLINICAL BENEFIT

The DePuy Synthes Spine ProTi 360°™ Interbody Systems implants and instruments are used to reduce patient pain, spinal instability, and compromised biomechanics of vertebral bodies in the spine.

DEVICE LIFETIME

The DePuy Synthes Spine ProTi 360°™ Interbody Systems have completed their treatment lifetime once the fusion mass has attained adequate strength to sustain the stability and integrity of the spinal segment without necessitating external support (typically six (6) to twelve (12) months depending on the condition(s) treated and the procedure performed).
The expected treatment lifetime of the DePuy Synthes Spine ProTi 360°™ Interbody Systems reusable instruments is dependent on many factors including the method and duration of each use and the handling between uses. Careful inspection and functional testing of the devices before use, as described in this document, is the best method for determining the reusable instrumentation end of life.

MATERIAL

Cervical implants are manufactured from implant grade Polyetheretherketone (PEEK, 91% volume) per ASTM F2026. The DePuy Synthes Spine ProTi 360°™ Interbody Spacer devices are constructed from Polyetheretherketone per ASTM F2026 and have a titanium plasma spray (8% volume) per ASTM F1580. Each implant contains Tantalum markers per ASTM F560 (1% volume). The specialized instruments are made primarily of surgical grade stainless steel (ASTM F899).

Lumbar implants are manufactured from implant grade Polyetheretherketone per ASTM F2026. The implants are provided in PEEK ASTM F2026 (92-93% PEEK volume) with a titanium plasma spray (6-7% volume) per ASTM F1580 on the endplates, or PEEK ASTM F2026 (85-95% volume) with a titanium plasma spray (5-15% volume) per ASTM F1580. All implants contain Tantalum markers per ASTM F560 (~1% volume). The specialized instruments are made primarily of surgical grade stainless steel (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 using the dose substantiated in accordance with ISO 11137-2 to achieve an SAL of 10^{-6}. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not resterilize.

The DePuy Synthes Spine ProTi 360°™ Interbody 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 ProTi 360°™ Interbody Systems implants should never be reused under any circumstances. Reuse may lead to infection or other negative outcomes.
5. DePuy Synthes Spine ProTi 360°™ Interbody system trials should never be used as an implanted device.
6. The DePuy Synthes Spine ProTi 360°™ Interbody System should never be used with dissimilar materials.
7. 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.
8. 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.
9. Implants with larger lordotic angles (i.e., ≥10°) are intended to be used with an anterior cervical plate as supplemental fixation.

PRECAUTIONS

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 post-operative 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 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 ProTi 360°™ 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, delayed union or pseudarthrosis;
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
18. Subsidence

Some adverse events may occur as part of the surgical procedure but are not related to the implanted device. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

[1] ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

A patient with the DePuy Synthes Spine ProTi 360°™ Interbody implants may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	DePuy Synthes Spine ProTi 360°™ Interbody Implants
Nominal value(s) of Static Magnetic Field (T)	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	19 T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-received coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [W/kg]	1.0 W/kg (Normal Operating Mode)
Scan Duration	1.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 12 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

DIRECTIONS FOR USE

The operating surgeon is solely responsible for determining 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 ProTi 360°™ Interbody Systems 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:

[2] Prolystica™ Ultra Concentrate neutral Detergent, a trademark of Steris Corporation, was used in the cleaning validation.

- 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 ProTi 360°™ Interbody System implants, use only the specialized DePuy Synthes Spine ProTi 360°™ 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 ProTi 360°™ Interbody Systems implants and instruments, please refer to the DePuy Synthes Spine ProTi 360°™ Interbody Systems Surgical Technique Manuals (provided with the system).

CARE AND HANDLING

Certain DePuy Synthes Spine ProTi 360°™ Interbody Systems Implants and all instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be cleaned and sterilized according to the standard hospital procedure. Refer to the CLEANING and STERILIZATION sections for recommended parameters.

Limitations on Processing

Repeated processing has minimal effect on these implants and instruments. End of life is normally determined by wear and damage due to use.

Point of Use

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.

Containment and Transportation

It is recommended that instruments are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning

Remove excess soil with a clean, lint-free, disposable, absorbent cloth.

Cleaning (Automated)

Equipment: Automated washer, soft bristle brush, enzymatic detergent[1], and neutral pH detergent[2].

- Preclean the instruments by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- After precleaning, place in the automated washer, making sure the samples do not touch each other - load instruments in such a way that the parts can drain.
- Use a standard instruments cycle with the following parameters (at a minimum):

Enzyme Wash	Hot (40 - 65 °C) (104 - 149 °F) for 3 minutes
Neutral pH Wash	60 °C (140 °F) for 3 minutes
Rinse	Ambient temperature for 1.5 minutes
Thermal Rinse	90 °C (194 °F) for 1 minute
Dry	82 °C (180 °F) for 6 minutes

- Determine if the instruments are dry. If they are not dry, dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat cycle or use manual cleaning. Replace an instrument that cannot be cleaned.

Cleaning (Manual)

Warning: Movable components and blind holes require particular attention during cleaning.

Preparation of Cleaning Agents (Recommended):

- Add 60 mL of Endozime® AW Plus to 3.8 L of water, (1:64 dilution).

Manual Cleaning Instructions:

- Preclean the instruments by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- Bathe the instruments in the enzymatic solution for 5 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the instruments with a soft bristle brush while submerged in the detergent.
- Rinse the devices in purified water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.
- Pat dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat manual cleaning. Replace an instrument that cannot be cleaned.

Inspection and Function Testing

Visually inspect all instruments under normal lighting. Inspect for surface damage and wear. Check for staining, discoloration, corrosion, misalignment, burrs, bent or fractured tips. Where instruments interface with other devices, inspect to ensure that the instruments properly interface. Mechanically test the working parts to verify that each instrument functions correctly. Replace any instrument that is not functioning.

Verify the legibility of all markings. Replace any instrument that is unreadable.

Device Replacement

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

Warning: Do not attempt to repair any DePuy Synthes instrument.

If your DePuy Synthes device is defective or damaged, contact your local DePuy Synthes Representative. In your correspondence please include, at minimum, the following:

- Device Part Number
- Device Lot Number
- Description of defect or damage
- Information on whether the device is available for return

PACKAGING FOR STEAM STERILIZATION

For sterilizing non-sterile instruments, the devices may be loaded into the specified DePuy Synthes instrument trays, or general-purpose caddies/trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are intended for pre-vacuum steam sterilization.

STERILIZATION

For devices 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. Do not re-sterilize.

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

Warning: The manufacturer does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, DePuy Synthes recommends the following parameters:

Sterilizer Type	Gravity	Pre-Vacuum	
Minimum Temp.	132 °C (270 °F)	132 °C (270 °F)	135 °C (275 °F)
Exposure*	15 min	4 min	3 min
Dry Time	20 minutes		

**The manufacturer has validated the above sterilization cycles and has the data on file. The validated sterilization parameters meet the minimum requirements per ISO 17665. Other sterilization cycles may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.*

The manufacturer recommends following ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, which includes: physical monitoring of the cycle, inclusion of a chemical indicator internal and external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

Certain DePuy Synthes Spine ProTi 360°™ Interbody implants are provided sterile and cannot be re-sterilized.

Storage

DePuy Synthes Spine ProTi 360°™ Interbody Systems instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

Disposal and Retrieval of Devices

Warnings and Precautions

When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. If an implant has been removed it is recommended that the device is returned to DePuy Synthes for investigation and disposal. The DePuy Synthes Spine ProTi 360°™ Interbody devices that have not been used in surgery do not contain materials that require special handling for disposal.

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. Please contact DePuy Synthes customer service for return of removed implants.

Disposal of Device

For disposal of a product following an error in storage or improper use of the product, implants must follow the pathway for removal of hospital waste products in compliance with the procedures enforced within the institution.

CUSTOMER SERVICE

For further information regarding the DePuy Synthes Spine ProTi 360°™ Interbody Systems or a copy of the DePuy Synthes Spine ProTi 360°™ Interbody Systems Surgical Technique Manuals, please contact DePuy Synthes or your local DePuy Synthes Distributor. To receive a printed IFU within 5 business days, please contact customerservice@proti360.info for DePuy Synthes Spine ProTi 360°™ Interbody Systems devices.

REPORTING OF SERIOUS ADVERSE EVENTS OR INCIDENTS

DePuy Synthes requests users and patients to report all Serious Event or Incidents to the manufacturer (see contact details below) and to your local Competent Authority.

A copy of the current device Summary of Safety and Performance Characteristics (SSCP) can be accessed (https://ec.europa.eu/tools/eudamed/#/screen/search-device)

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LBL-DS202516-EN REV B-01 (2025-09-18)

SYMBOL GLOSSARY

SYMBOL	MEANING
	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
	Date of Manufacture / Country of Manufacture
	Expiration Date
STERILE R	Sterilized Using Irradiation
	Do Not Re-Use
	Do Not Use If Package Is Damaged
	Do Not Re-Sterilize
	Consult Instructions for Use
	Non-Sterile
	Distributor
	Manufacturer
CE 2797	CE Mark / CE Mark with Notified Body
EC REP	Authorized Representative in the European Union
CH REP	Authorized Representative in Switzerland
UDI	Unique Device Identifier
MD	Medical Device
	Double Sterile Barrier
	Patient Identification
31	Date Information was Entered or Procedure Took Place
	Health Care Centre or Doctor
	Patient Information Website
MR	MR Conditional