English

Instructions for use

ProTi 360°™ INTERBODY SYSTEM

INSTRUMENTS

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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 instruments are delivered non-sterile.

INDICATIONS FOR USE

The DePuy Synthes Spine Instruments are used in conjunction with the DePuy Synthes Spine ProTi 360°™ Interbody System. Specific indications are provided in the appropriate DePuy Synthes Spine ProTi 360°™ Interbody System Package Insert.

MATERIAL

The specialized instruments are made of surgical grade stainless steel (ASTM F899).

HOW SUPPLIED

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

Specific contraindications are provided in the appropriate DePuy Synthes Spine Implant System.

WARNINGS and POTENTIAL RISKS

The surgeon should be aware of the following:

1. The surgeon must ensure that all necessary 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.
2. All instruments must be cleaned and sterilized prior to surgery.

PRECAUTIONS

℞ Federal law restricts this device to sale by or on the order of a physician.

Preoperative:

1. Care should be used in the handling and storage of the instrument components. The instruments should not be scratched or otherwise damaged. Instruments should be protected during storage especially from corrosive environments.
2. All instruments should be cleaned and sterilized before use.

Intraoperative:

1. Any instruction manuals should be carefully followed.

POSSIBLE ADVERSE EFFECTS

1. fracture of the instruments;
2. sensitivity to a metallic foreign body, including possible tumor formation;
3. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
4. infection;
5. nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
6. gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
7. pain or discomfort;
8. hemorrhage of blood vessels and/or hematomas;

DIRECTIONS FOR USE

The operating surgeon draws up an operating plan that specifies and appropriately documents the following steps:

- Selection of the instrument components and their dimensions
- Positioning of the instrument components in the bone
- Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:

- All requisite instrument components are ready to handle
- Operating conditions are highly aseptic
- The instruments are cleaned and sterilized prior to use according to the procedures outlined in this document.
- The 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 handle.
- 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.

For complete instructions regarding the proper use and application of all DePuy Synthes Spine implants and instruments, please refer to the DePuy Synthes Spine ProTi 360°™ Interbody System Surgical Technique Manual (provided with the system).

CARE AND HANDLING

All instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Limitations on Processing

Repeated processing has minimal effect on 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, disposable, absorbent Kimwipe or equivalent.

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.
- Final rinse shall be performed in purified water at room temperature for 5 minutes.
- The rinse bath should be changed after each cleaning process.

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).

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

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

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.

Maintenance and Repair

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 Spine instrument.

If your DePuy Synthes Spine instrument requires repair or maintenance, return the instrument in the DePuy Synthes Spine box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767
Attn: DePuy Synthes Spine Technical Services

Note: Instruments returned to DePuy Synthes Spine must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

Inspection and Function Testing

All instruments: Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.

Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.

Packaging

Instruments may be loaded into the specified DePuy Synthes Spine instrument trays, or general-purpose trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA approved for pre-vacuum steam sterilization.

Sterilization

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

Warning: DePuy Synthes Spine 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 Spine recommends the following parameters:

Sterilizer Type	Gravity	Pre-Vacuum	
Minimum Temp.	132℃ (270℉)	132℃ (270℉)	135℃ (275℉)
Exposure*	15 min	4 min	3 min
Dry Time	20 minutes		
**DePuy Synthes Spine has validated the above sterilization cycles and has the data on file. The validated sterilization parameters meet the minimum requirements per ISO 17665-1. 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.*			

DePuy Synthes Spine 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.

Storage

DePuy Synthes Spine 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.

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
QTY	Quantity
	Non-sterile
	Do not use if package is damaged
	Consult instructions for use
	Caution
DIST. BY	Distributed by
CC	Date of manufacture
	Manufacturer
CE 2797	CE mark
CE	
EC REP	Authorized representative in the European Union
MD	Medical device
UDI	Unique Device Identifier

CUSTOMER SERVICE

For further information regarding the DePuy Synthes Spine ProTi 360°™ Interbody System or a copy of the DePuy Synthes Spine ProTi 360°™ Interbody System Surgical Technique Manual, please contact DePuy Synthes Spine or your local DePuy Synthes Spine Distributor.