

**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

Information for the Patient

The Patient Implant Card provided in the packaging with the implant is intended for EU, UK, and Swiss patients implanted with the DePuy Synthes Spine ProTi 360°™ Interbody Systems (Common Name: Cage). It allows patients to identify themselves as having such device and to be able to inform their healthcare providers of its device identification and its MRI safety status.

The Patient Information Leaflet on Page 3 is intended for EU, UK, and Swiss patients implanted with the DePuy Synthes Spine ProTi 360°™ Interbody Systems (Common Name: Cage). It provides device and post-operative information that the patient should be aware of.

Additional copies of the Patient Information Leaflet and replacement Patient Implant Card can be obtained at <https://proti360.info/>.



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<https://proti360.info/>

Instructions for the Healthcare Centre or Physician:

1. Peel provided Patient Implant Card (see Figure 1) from wax paper backing
2. Fold along perforated line
3. Fill in Patient Identification, Date of Surgery and Healthcare Centre and/or Doctor name on the front of the card.
4. Place the designated Implant Card Patient Label that was distributed with the device on the back of the card in the designated box.
 - a. The Patient Label intended for placement on the Patient Implant Card is identified by the IC on the Patient Label (see Figure 2 with highlighted IC Identifier)
5. Provide the Patient Implant Card to the patient.
6. Recommend that the patient always carry the Patient Implant Card with them.

Figure 1: Example Patient Implant Card

Please note, this figure is not to scale and not intended to be printed as the Patient Implant Card.

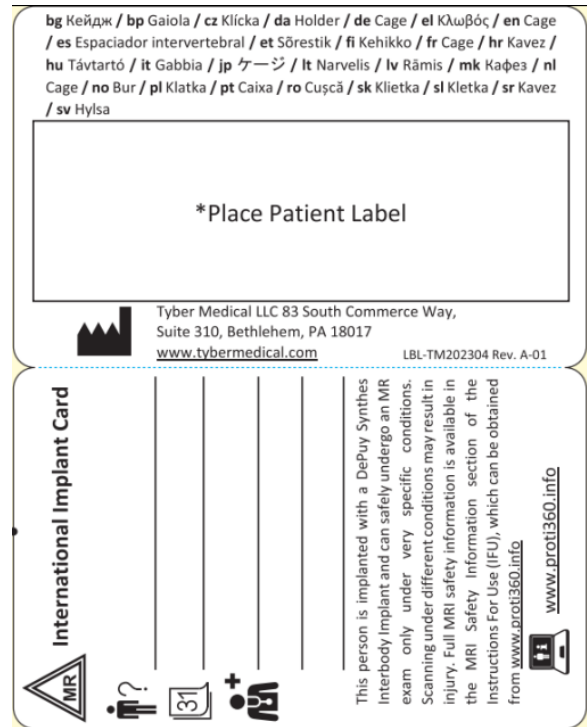


Figure 2: Example Patient Implant Card Patient Label

Please note, this figure includes a highlight to help in locating the IC designation on the Patient Label. This highlight will not be present on the provided Patient Label.



Patient Information Leaflet for the 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

Your provider gave you a card to carry around. You should always carry this card with you. It includes important information about the device implanted in you. Contact your provider if you need a new card.

This document has information on your device. Call your provider if you think you are having side effects from the device or if you have concerns. This document does not replace a visit with your provider. Contact your provider if you need another copy.

Magnetic Resonance Image (MRI) Safety

Tell your provider that you have an implanted device before an MRI exam. You can show them your card.

Limitations

Your provider will tell you any limitations related to the implanted device.










Expected Lifetime and Patient Follow-up

Follow up with your provider as instructed. Your time to heal may not be the same as other people. Your provider may decide to keep the implant in your body forever or may decide to remove the device.

Material

The devices are made of plastic or plastic covered in metal both of which have been used for a long time. This plastic or plastic covered in metal is shown to be safe when used in humans. Based on the current knowledge of the overall qualitative and quantitative patient exposure information.

Symbols on Patient Implant Card

Symbol	Title
	Medical Device / Reference Number
	Lot Number
	Unique Device Identifier
	Patient Identification
	Date Information was Entered or Procedure took Place
	Healthcare Centre or Doctor
	Patient Information Website
	MR Conditional
	Manufacturer



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