



Implant Cards – Instructions for Healthcare Organizations

Foreword

Aptis Medical as legal manufacturer of the Aptis Distal Radio Ulnar Joint (DRUJ) Prosthesis must provide Implant cards and product safety information to the patients. This leaflet provides indications on how to fill in implant cards and provide information to the patient.

In Europe, European Economic Area, Switzerland, USA and Australia the implants must be accompanied by an implant card. Aptis Medical provides these cards inside the packages of the Aptis DRUJ Prosthesis.

After implantation of an Aptis Medical implant the surgeon or treating physician shall provide the implant card duly compiled to the patient and provide adequate information related to safety, the post-operative precautions and required regular and extraordinary follow-up visits.

Implant Card:

The following picture shows an example of the unfolded two sides of the implant card.

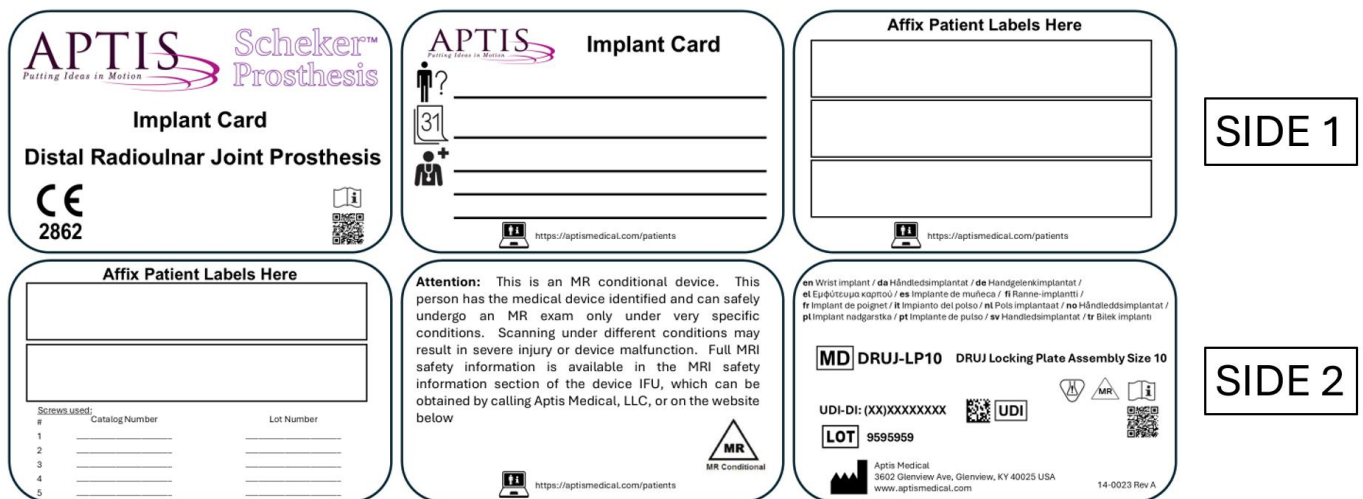


Figure 1: unfolded implant card sides

To fold the implant card, please follow the three steps illustrated in Figure 2.

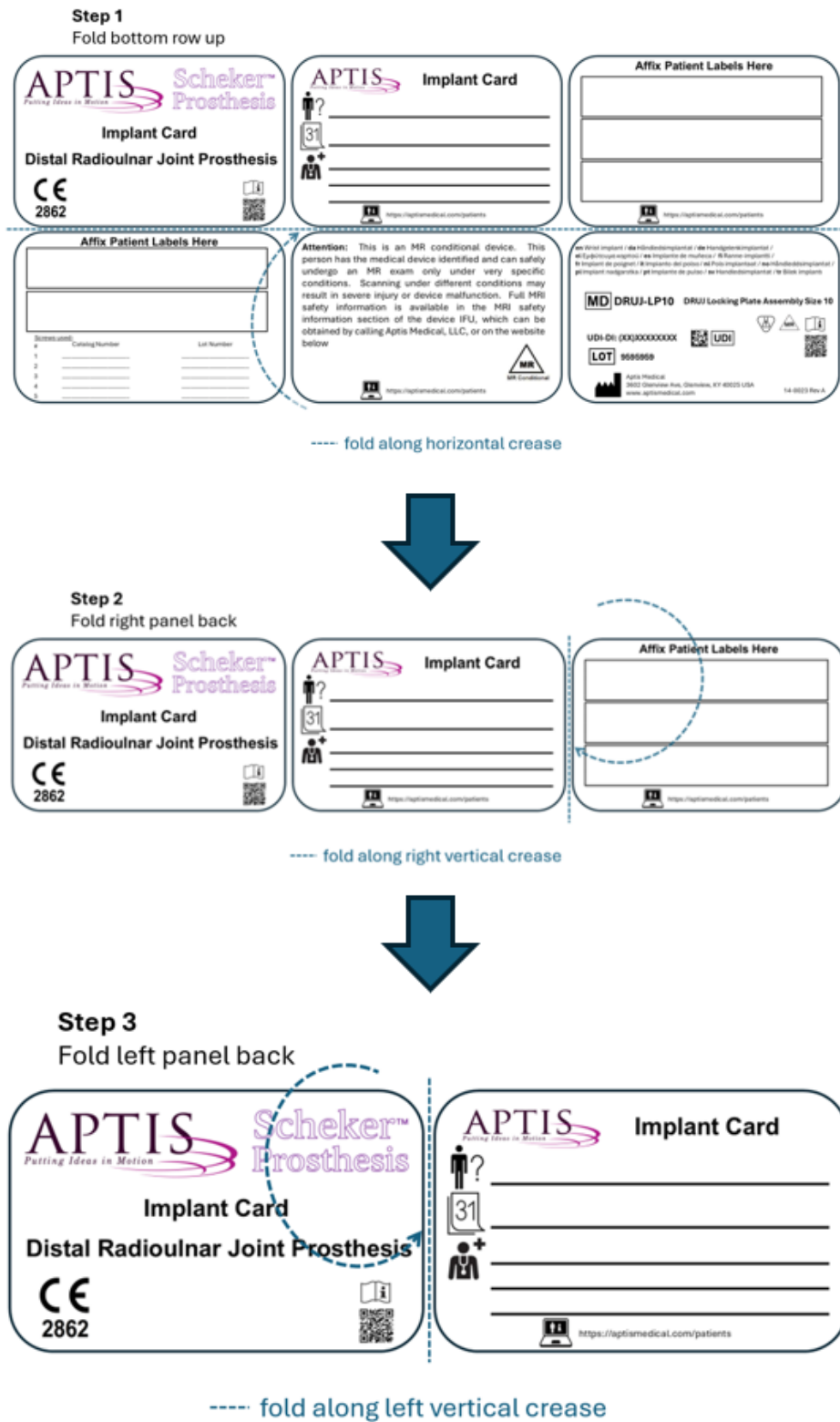


Figure 2: steps to fold implant card to credit card size



First Surgery

After surgery the implant card must be filled in and labels of Aptis Medical products implanted must be stuck in the appropriate places as shown in the following examples:

Figure 3: example filled card

Figure 4: example labels placement

Please handwrite the catalog and lot numbers for implanted screws, as seen in Figure 5.

#	Catalog Number	Lot Number
1	DRUJ-LSC22	0921
2	DRUJ-LSC14	0622
3	DRUJ-LSC16	0324
4		
5		

Figure 5: example filled screw info

The meaning of symbols is provided in the section at the end of this leaflet.

To fill in the implant card a standard pen can be used, however it is recommended to use permanent ink pens.

In principle only labels belonging to implants from Aptis Medical should be attached on the implant card. Do not stick labels of instruments.

If label space is insufficient, please provide a second implant card. We recommend you have spare implant cards which can be ordered at Aptis Medical and are delivered free of charge.

Explant / Revision Surgery











In case of explantation of one or more components and subsequent substitution of any component the implant card shall be updated by striking the components that are explanted and writing the date of explantation (see following example). A new implant card shall be completed for any new components that are implanted.

Figure 6: example for explanted components



Please remind the patient to make a photocopy or a scan copy of the implant card and conserve this copy in a safe place away from sources that can deteriorate it.

Explanation of symbols on the Implant Card

	Manufacturer		Catalogue Number
	Unique Device Identification		Lot number
	Medical Device		MR Conditional
	Patient identification		Date of operation
	Health care center and/or doctor		Patient information website