



## Implant Card Patient Information

### **Name and Model of Device**

Blue Sky Bio, LLC Dental Implant System (The specific name and model of the implant(s) used during your procedure is located on the implant card that you were provided post-surgery)

### **Product Features**

The Blue Sky Bio, LLC Implant System encompasses a diverse assortment of implants, associated prosthetic parts, instruments, and accessories. Within this range, the Blue Sky Bio, LLC Implant System offers several unique designs. These implants are tailored to promptly support a fixed or removable prosthesis in patients with either complete or partial tooth loss. Blue Sky Bio, LLC implants and prosthetic components are manufactured from a biocompatible titanium alloy. The implants and prosthetic components are available in various lengths and diameters, catering to diverse patient anatomies and dental deficiencies.

### **Purpose**

The primary purpose of the Blue Sky Bio, LLC Implant System is to provide support for permanent or removable dental prosthetics to restore chewing function.

### **Performance Expectations**

Recommended placement of Blue Sky Bio, LLC Implant System is in all areas of the mouth to support a fixed or removable dental restoration. Anticipated lifespan of the implant is longer than 10 years, which might be reduced due to factors like prosthesis overload, chemotherapy, or radiotherapy. Once integrated, the risk of implant failure decreases significantly. Regular evaluations and upkeep, including verifying the prosthesis' fit, are strongly advised.

### **Performance Changes**

Clinicians must educate patients about potential contraindications, side effects, precautions, and the importance of consulting a qualified dental professional if there are changes in implant performance, such as prosthetic looseness, infection, pain, or unforeseen symptoms.

If you have any issues with medications, dietary changes, oral hygiene, adverse effects, residual side effects or anything you consider related to the dental procedure contact your clinician.

## **Postoperative Care**

### Medication

Your surgeon will provide or suggest medication for effective pain relief.

### Diet

Post-surgery, it's vital to safeguard the implants by avoiding disturbing the surgical site. Surgeons typically recommend a soft diet for several weeks. Maintaining good oral hygiene is crucial for optimal healing.

### Oral Hygiene

Individuals with implants should prioritize rigorous lifelong oral hygiene practices. This ensures healthy gingival tissues around the implant, preventing plaque buildup around the implants and associated prosthetic components as well as natural teeth. Adhering to dental professional advice for routine check-ups and professional cleanings post-implant treatment is essential. Consult your dental professional for tailored and detailed care guidelines.

## **Possible Adverse Effects**

Temporary symptoms might include pain, swelling, speech difficulties, and gingival inflammation. More enduring issues can encompass allergic reactions to implant or abutment materials, implant or abutment breakage, loosening of screws, infections necessitating implant revision, nerve damage causing lasting weakness, numbness, or pain, implant loosening necessitating revision surgery, sinus perforation, labial and lingual plate perforation, and bone loss potentially leading to revision or removal.

## **Residual Risks and Precautions**









The practitioner bears the responsibility for appropriate patient selection, adequate training, experience in implant placement restoration, and furnishing informed consent information. Incorrect technique can result in implant failure, nerve/vessel damage, or bone loss. Implant failure rates rise when placed in irradiated bone due to radiotherapy-induced progressive fibrosis of vessels and soft tissue, impairing healing capacity.

## **MRI Safety**

While these products have not undergone MRI safety testing, literature analysis indicates that scanning a Blue Sky Bio, LLC Implant System poses no significant risks under specific conditions and are considered as "MR Conditionally Safe" under the following scanning conditions:

- Static magnetic field strengths of  $\leq 3$  Tesla
- Magnetic field gradients up to 30T/M (3000G/cm).
- RF Excitation:  
Circularly Polarized (CP) for all landmarks above umbilicus - No excitation restrictions for all landmarks below the umbilicus
- Operating Mode: Normal Operating Mode in the allowed imaging zone
- Whole-body specific absorption rates (SAR) of 2W/kg
- Maximum Head SAR: Not evaluated for head landmark
- Scan Duration: No specific constraints due to implant heating

## Implant Card Symbol Translations

	Patient Name or Patient ID
	Date of implantation
	Name and address of the implantation healthcare institution / provider
	Name and address of manufacturer
	Information website for patients
	Device Name
	Lot Number / Batch Code
	UDI as AIDC format

### **Manufacturer**

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