

 Panthera Dental Inc.
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Panthera Dental Bar Instructions for use – Dental Practitioner Guide



This notice is not intended to replace or supersede sound medical, dental practitioners' experience or training. Panthera Dental does not provide medical advice.

Panthera Dental Bars

- Panthera Dental Dolder Bar
- Panthera Dental Hader Bar
- Panthera Dental Milled Bar
- Panthera Dental Paris Bar
- Panthera Dental Wrap-Around Bar
- Panthera Dental Montreal Bar
- Panthera Dental Montreal Bar with Metallic Lingual
- Panthera Dental Pin Lingual Bar
- Panthera Dental Pin Wrap-Around Bar
- Panthera Dental RE Bourke Concept Bar
- Panthera Dental Integrated Bar

Description: The Panthera Dental bar is an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient for purpose of restoring chewing function.

Materials: The Panthera Dental bar is made of titanium Ti6Al4V, grade 5, certified ASTM F1472-14¹.

Packaging content: One (1) dental bar with screws or attachments, if applicable.

Indications for use: The Panthera Dental Milled Bar is indicated for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient for purpose of restoring chewing function. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained.

Contraindications:

- Number of implants-abutments < 2 and > 10
- Unwillingness of the patient to follow the aftercare / recall instructions
- Patient with allergies to one or more elements of the attachment materials
- Patient with bruxism or other uncontrolled parafunctional habits
- Refer to the implant manufacturer's user guide for further contraindications

Attention: It is the responsibility of the dental practitioner to choose the proper bar according to the prosthetic project. For safe and effective use of the device, it should only be installed by a trained professional. A yearly verification of the bar is recommended to maintain the top level quality offered by the Panthera Dental line of products. Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

Directions for use: Firmly screw the bar into the implants using the appropriate dynamometric extension tool. Ensure that insertion is adequate. Refer to the instructions for use of the third-party screw and/or attachment manufacturer for the specific numerical insertion torque requirements. Please note that Panthera does not torque any screwed attachments before delivery.

Storage and transport: Keep inside the original box at room temperature, in a clean and dry place whenever possible. The product does not have an expiration date. Dispose of the product according to local / national regulatory guidelines.

Warning: These instructions for use are not sufficient for the appropriate use of the dental bar; knowledge in dentistry and dental techniques are also required for its good use. Any use failing to comply with these instructions is considered inappropriate.

European, U.S., and Canadian Federal Laws restrict this device to sale by or on the order of a licensed dentist or physician.

Sterilization: The dental bar is sold NON-STERILE. It is the responsibility of the dental practitioner to clean the bar before its use, in conformance with the general dentistry practices. All Panthera Dental bars must be sterilized before use with the validated following cycle: Pre-vacuum steam sterilization for wrapped instruments, 4 minutes at 132°C, followed by a drying time of 30 minutes. The validated sterilization process should be performed in a validated sterilizer and the use of it should be in accordance with a recognized sterility assurance standard such as ANSI/AAMI S779:2010/A4:2013².

Maintenance and constant care: Dental practitioners have the responsibility to maintain the functionality and proper storage of the device, while ensuring the safety of the patient with constant care.









Safety, responsibility and warranty: Bars provided by Panthera Dental are manufactured in accordance with European, American and Canadian standards for medical devices. No adverse effects are expected or reported. Physiological and anatomical patient conditions may negatively affect the performance of the device. The Panthera Dental bar has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Panthera Dental bar in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Guideline for the patients: Patients are recommended to follow the indications provided by the dental practitioner, go for periodic checks and maintain proper daily dental hygiene.

Technical assistance: Our technicians are available to answer any questions on the use of the Panthera Dental products. You may contact our customer service. Further information concerning the use of the dental bar is available in our product catalog and in the technical data sheets.

Reference:

1. ASTM F1472-14, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications*
2. ANSI/AAMI S779 :2010/A4 :2013, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

	Manufacturer		Prescription only
	Authorized representative in the European Community		Consult instructions for use
	Do not re-use		Keep dry
	Non-sterile		Batch code

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






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