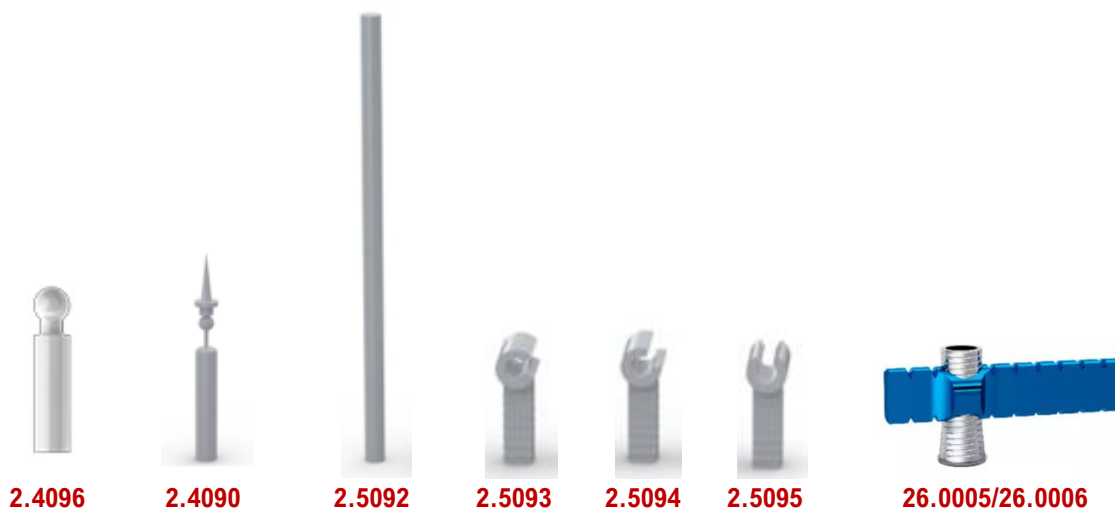


## INSTRUCTIONS FOR USE



**ATTENTION:** The figures are merely illustrative. They do not represent the actual dimensions.

This device is intended for a specialized procedure, which must be performed by qualified professionals in Dental Implants. For best results, use the product knowing the appropriate techniques. Always apply them in appropriate conditions, also in an operating room environment. They are prosthetic components indicated for the manufacture of prostheses, used in the laboratory, to cast the base of the elements that will be used in intraoral rehabilitation.

## INDICATIONS FOR USE

The Clip Bar is indicated to offer support for removable total dentures on implants, according to the available interocclusal space and three-dimensional position and distribution of the implants. It can be used in immediate or conventional rehabilitation procedures, in maxilla or mandible. They are pieces indicated to join the endosseous implants and/or remaining natural teeth, with the help of the uclas or cylinders forming a kind of bridge (bar), in order to offer retention for the total prosthesis. The Clips are indicated to connect the prosthesis to the Bar.

## DEVICE DESCRIPTION

The prosthetic components of the clip bar system are manufactured in Pom Copolymer (Plastic), sold individually or in kits, non-sterile, packaged in thermosealed blister.

## PRESENTATION

Code: 2.4096 - 1 unit of Oring Pin  
Code: 2.4090 - 1 unit of Oring Pin with Root  
Code: 2.5092 - 1 unit of Clip Bar 50 mm  
Code: 2.5093 - 1 unit of 70° Clip  
Code: 2.5094 - 1 unit of 35° Clip  
Code: 2.5095 - 1 unit of Straight Clip  
Code: 26.0005 - 1 unit of extension bar for mini pillar  
Code: 26.0006 - 1 unit of Extension Bar for HE

Code: 2.5096  
1 unit of 70° Clip  
1 unit of 35° Clip  
1 unit of Straight Clip  
1 unit of Clip Bar 50 mm

## CONTRAINDICATIONS

This product is contraindicated if there is insufficient interocclusal space and unsatisfactory three-dimensional position of the implant.

## HOW TO USE

Perform the molding of the implants/components with the help of the corresponding transfer, according to appropriate techniques. On the analogues, position the Calcifiable Cylinders or Uclas that can be customized, according to the need and available interocclusal space.

Perform the waxing using the Casting Bar.

Carry out the process of casting the Bar according to appropriate techniques.

Install the Cast Bar in the mouth and fit the Clip. Perform a wear (relief) in the region of the prosthesis that will receive the Clip.

Perform a test of the prosthesis to verify its adaptation to the set.

Capture the Clip in the mouth with acrylic resin, keeping the prosthesis in occlusion until the resin is completely polymerized.

Remove the prosthesis and finish the prosthesis. In the mouth, the fused bar will remain and in the prosthesis, the clip.

## PRECAUTIONS

- It is advisable that the final denture be cleaned before installation in the mouth.
  - The Clip should be replaced regularly when it loses function.
  - Instruct the patient to attend the office regularly, to verify the retention of the prosthesis.
  - Non-sterile product. Single use. The reuse of this product may cause:
  - adverse biological effects resulting from product residues, microorganisms and/or substances resulting from previous uses and/or reprocessing;
  - The structure of the parts used for the process of making the prosthesis undergo changes in the original physical, mechanical and chemical, macro and micro structural characteristics of the product that may impair its intended functionality.
- Reuse of this product does not guarantee its safety and effectiveness.
- Do not use the product if the packaging is tampered with.
  - Do not use the expired product.
  - Make sure that the parts are not swallowed or inhaled by the patient.
  - It is the responsibility of the dentist to use DSP Biomedical products in accordance with the instructions for use.
  - Better results are achieved with the use of the DSP Biomedical product sequence. The use of instrumentation and/or prosthetic components from other manufacturers does not guarantee the perfect functioning of the DSP Biomedical implant system and voids any product warranty.

## ADVERSE EFFECTS

No adverse effects are expected as long as the product is used according to its instructions for use.

## ADDITIONAL INFORMATION FOR THE PROFESSIONAL

Instruct the patient about the need for professional medical follow-up after surgery and obey the guidelines regarding care, hygiene and prescription of medications. These guidelines are the responsibility of the responsible professional.

## PRESENTATION AND STERILIZATION

This product is indicated for single use and supplied non-sterile, individually packaged.

## PRODUCT CLEANING

This product must be properly sanitized and sterilized after casting.

To clean the DSP abutments, use only the following manual cleaning process. Automated cleaning has not been validated. Do not use automated cleaning for DSP abutments.

1. Disassemble the pillar and screw (if applicable).
2. Prepare Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner according to the manufacturer's recommendation of 1ml/L of warm tap water.
3. Soak the items in the prepared detergent solution and let them soak for at least 1 minute. While soaking, brush the items with a soft-bristled brush.
4. Prepare Prolystica® 2X Presoak and Cleaner Enzyme Concentrate according to the manufacturer's recommendation of 1ml/L in warm tap water in a sonication unit.
5. Soak the articles in the prepared detergent solution and let them sonicate for 10 minutes.
6. Visually inspect each test article for visible soil. If any visible dirt remains, repeat the cleaning process (steps 4-8) until there is no more visible dirt.

## STERILIZATION

Sterilize the products the day before or on the day of the procedure.

ATTENTION: It is not recommended to autoclave these products in their original packaging. The product must be packaged with a wrap approved by legislation.

Please use for sterilization only steam sterilization according to the following parameters:

<b>DYNAMIC/FRATIONATED VACUUM AIR REMOVAL PARAMETERS<sup>1</sup></b>	
Sterilization time	4 minutes
Temperature	132°C
Drying time	20 minutes <sup>2</sup>

<sup>1</sup> At least three vacuum steps.

<sup>2</sup> The drying time actually required depends directly on the parameters of the user's sole responsibility (load configuration and density, sterilizer conditions) and must therefore be determined by the user. However, drying times of less than 20 min should not be applied.

### TRACEABILITY LABEL

This product is accompanied by three labels that allow its traceability and must be attached to the following documents: • patient record;

- prosthetic records;
- implant card;

Identification and traceability are carried out through the REF and LOT codes.

### STORAGE CONDITIONS

This product should be stored in its original packaging, in a clean and ventilated place, at a maximum temperature of 45°C, and protected from direct sunlight.

### MATERIAL DISPOSAL

All products and consumables used during surgery to install dental implants can put the health of those who handle them at risk after use. Before disposing of them in the environment, it is recommended to observe current legislation and comply with it.

### SHELF LIFE

This product has an estimated life span of 8 years.

### EXPIRATION DATE

See on label.

### PRODUCT WARRANTY









DSP Biomedical provides product warranty against any manufacturing defect. The presence of any defect must be immediately reported to the manufacturer, respecting the legal deadline. The warranty of products manufactured by DSP Biomedical is strictly linked to following the information described in the instructions for use. Improper use of the product in disregard of the indications exempts the manufacturer and/or seller from any responsibility.


















Note: the warranty does not cover wear and tear resulting from the use of the product.

### SERVICE INFORMATION

If there is a need for more information, or the product presents any adverse effect, with potential risk to the patient, which generates or has the potential for injury or threat to public health, or any customer dissatisfaction, please contact DSP at 0800 600 88 66, or send an email to [sac@dspbiomedical.com.br](mailto:sac@dspbiomedical.com.br).

### SYMBOLOLOGY

SYMBOLOLOGY	DESCRIPTION	SYMBOLOLOGY	DESCRIPTION
	Batch number		Refer to the instructions for use or refer to the electronic instructions for use
	Date manufacturing		Manufacturer
	Non Sterile		Keep in a dry place
	Product Code		Keep out of sunlight

	Model Number		Unique sterile barrier system
	Do not reuse		Expiration date
	Temperature Threshold		Unique Device Identifier
	Authorised representative in the European Community		Country of manufacturer
	Care		Do not use if packaging is damaged and refer to instructions for use
	Importer		Humidity limits
	Fragile, handle with care		Medical Device
	CE Mark		FDA-Required Prescription Notification for the United States States Market
	CE marking with Notified Body number; SIQ, number 1304		

**REF :Goods**

Device Description	Code
Bar Clip 50mm	2.5092
Calcinable Oring Pin	2.4096
Root Oring Pin	2.4090
70° clip	2.5093
35° clip	2.5094
Straight Clip	2.5095
Extension Bar for Mini Pillar	26.0005
Extension Bar for Ucla	26.0006
Clip Bar Set	2.5096

**MANUFACTURED BY**

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