Bionnovation
implantes

CE 0434

Universal
Pillar's Protractors

EC REP

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MADE IN BRAZIL / INDÚSTRIA BRASILEIRA / INDUSTRIA BRASILEÑA

www.bionnovation.com.br

Data de Fabricação
Fecha de Fabricación
Date of Manufacture

REF
Código do Produto
Código del Producto
Product Code

LOT
Número do Lote
Número de Partida
Batch Number

Prazo de Validade
Fecha de Fabricación
Date of Manufacture

Manter afastado do sol
Mantener fuera de la luz solar
Keep away from sunlight

Consulte as instruções de utilização
Consulte las instrucciones de utilización
Refer to instructions for use

CE 0434
Marcação CE para Comercialização na Comunidade Européia
Marca CE para Comercialización em la Comunidad Europea
CE Mark for European Community Market

Manter seco
Mantenga seco
Keep dry

Não reutilizar
No reutilizar
Do not reuse

STERILE EO
Esterilizado por óxido de etileno
Estéril por óxido de etileno
Sterilized using ethylene oxide

EC REP
Representante europeu autorizado
Representante europeo autorizado
Authorised representative in the european comunity

Não utilizar se a embalagem estiver danificada
No usar si el paquete está dañado
Do not use if package damaged

Fabricante
Fabricante
Manufacturer

DESCRIPTION AND OPERATIONAL FOUNDATIONS
The casting protractor allows reproducing the angulations and the exact location of the universal pillar for the prosthetic work model, from its waxing to the making of the final prosthesis.
The risk factors applicable to the casting protractor's utilization are practically nonexistent, when it is correctly used for the proper destination and when the directions are followed.

Accessories
Not applicable

PRODUCT'S COMPOSITION
The Casting Protractors are made of Polyacetal Copolymer or Polyoxymethylene, also known as POM.

DIMENSIONS/VOLUMES
The universal pillar's casting protractors are available in of Ø 3,5 and 4,5-mm diameters at 4,0 and 6,0-mm heights. Protractors with 4,0-mm heights are available in the color yellow, and protractors with 6,0-mm heights in the color blue.

INDICATIONS AND PURPOSE OF USE
Made of Polyacetal Copolymer or Polyoxymethylene, also known as POM, the casting protractor's purpose is to transfer the component's exact position (universal pillar) to the prosthetic work model.

PRECAUTIONS, RESTRICTIONS AND WARNINGS
WARNINGS:
1. STERILE, provided the packaing has not been violated, and the validity term and storage conditions are fulfilled.
2. FOR PROFESSIONAL USE ONLY – only qualified professionals with knowledge on surgical techniques and on the procedures necessary for the product's adequate utilization should use the protractors.
3. IT'S FORBIDDEN TO REUTILIZE, RESTERILIZE OU REPROCESS THE PRODUCT – if it's reutilized, resterilized or reprocessed there may be an alteration of the protractor's color, including melting, fragility increase, alteration of its physical-chemical properties, and alteration of its dimensional characteristics. Bionnovation does not recommend its reutilization, resterilization or reprocessing, and discard it according to the applicable legislation for hospital waste, do not discard contaminated products in the common litter.
4. The use of the product with surgical techniques and under inadequate biosafety conditions may harm the patient leading to unsatisfactory results.
5. In all operations involving protractors please observe the appropriate asepsis and antisepsis techniques.
6. The abusive use of alcohol, tobacco, drugs, and corticoids, or a lack of adequate oral hygiene may significantly affect treatment's success.
7. The protractors must only be utilized for their original purpose.
8. Casting protractors are supplied in a sterile double packaging (ETO). Provided the packaging has not been violated, it will keep the product sterile for up to 4 years to be counted as of the sterilization date.
9. In the case of adverse effects verified in the patient, the responsible professional must immediately contact Bionnovation's CSH (Customer Service Hotline) at **0800 770 3824** or through the e-mail **sac@bionnovation.com.br.** Bionnovation Produtos Biomédicos is responsible for notifying ANVISA (the Brazilian National Sanitary Surveillance Agency) on the pertinent occurrences according to its internal technovigilance procedure.
10. The protractors have been developed in order to avoid that its use might compromise patients' clinical status, as well as their safety.
11. In the case of impact and if the same presents high intensity scrapes, fissures or cramples, which might hinder the product's proper functioning, the same must be discarded and a new product must be acquired.
Note: We recommend that the identification adhesive labels that come with the product are annexed to the documentation to be delivered to the patient, to the clinical record and to the fiscal documentation related to billing.

PRECAUTIONS:
1. It's supplied in sterile state and after it has been opened it must be used under aseptic conditions. You must always work with sterile fields, appropriate instruments for the procedure and in good state of conservation in order to eliminate infection sources.
2. Inspect any and every device before using it, in order to visually verify if the same has not been damaged.
3. The manufacturer will not be responsible for damages that may eventually occur in the product and consequently to the patient, due to incorrect handling or inadequate use of the same.
4. Disposal: the product's disposal must comply with the environmental and biosafety laws in force. Do not discard contaminated products in the common litter.

STERILITY
Casting protractors are supplied in the STERILE form (Ethylene Oxide). Provided the packaging has not been violated.

SPECIAL CONDITIONS FOR THE PRODUCT'S STORAGE AND TRANSPORTATION, CONSERVATION AND/OR HANDLING.
Storage conditions
Store it away from direct sunlight, and sources of heat and humidity. Keep the packaging sealed until its use. Make sure the packaging has not been violated before utilization. Do not use it if the sterile package has been opened or is damaged, or if its sterilization validity date has expired, to avoid possible contamination. Discard any mischaracterized product according to applicable legislation for hospital waste, or return the damaged packages, including the device, to the manufacturer.

Transpotation conditions
Transport it in the original packaging and away from direct sunlight and sources of heat and humidity, and no not let it fall in order to avoid any damage to the product.

HANDLING CONDITIONS
In the case of any alteration in the casting protractor's characteristics, discard it in mischaracterized form according to applicable legislation for hospital waste or return the damaged packages, including the device, to the manufacturer.

COMMERCIAL PRESENTATION FORMS

A sterile casting protractor made of polyacetal, packaged in sealed blister with Tyveck® as primary packaging and with an identification adhesive label, 03 adhesive labels with the product's traceability information that must be annexed to the clinical record, to the document to be delivered to the patient, and to the fiscal documentation for billing, and as final packaging, a sealed heavy stock cardboard paper box, and 02 adhesive labels affixed to the lid (01) and to the box's frontal part (01).
The product comes in different diameters and heights, allowing it to be adequately selected and utilized for each surgical procedure.

USE INSTRUCTIONS

After installing the universal pillar on the Morse Cone type graft. Position the protractor on the Universal Pillar until it has been locked and transfer the universal pillar's position to the prosthetic work model. To obtain the model, use a device analogous to the corresponding universal pillar.