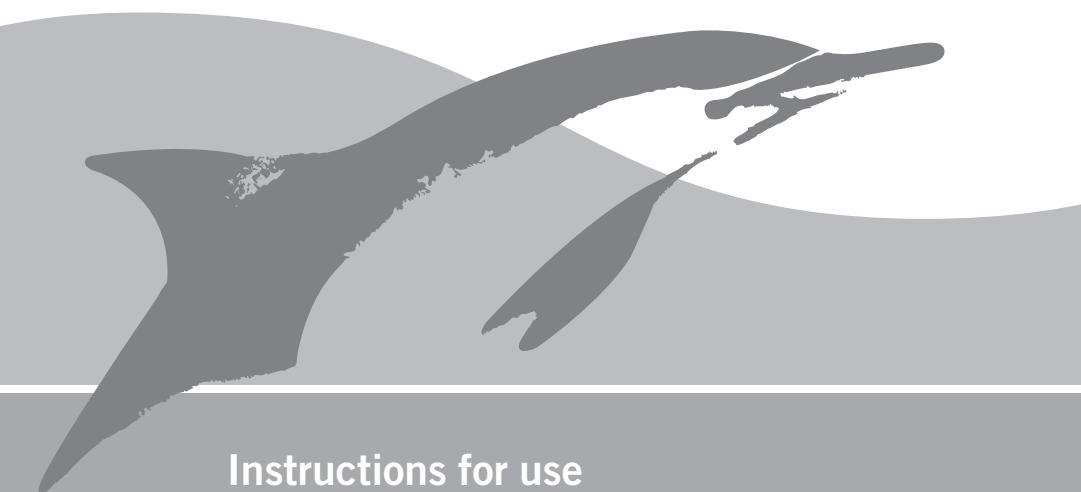


Heraeus

Medical

PALAGUN®

Bone Cement Mixing System –
Disposable Cement Gun

A stylized, dark gray silhouette of a bird, possibly a penguin or a similar large seabird, is shown in flight. The bird is positioned horizontally, facing right, with its wings spread wide. The background consists of two large, overlapping, light gray circular shapes that create a sense of depth and movement. The bird's body is dark gray, and its wings show some internal detail with lighter gray shading. The overall composition is minimalist and modern.

Instructions for use

Device name: **PALAGUN® Bone Cement Mixing System**

Type: **CL006-02**

REF: 5082371

1. Product description

PALAGUN® is a sterile disposable cement gun and is intended to accommodate mixing cartridges to ensure precise and effortless application of the bone cement. The mixing cartridges of the following products can be used: **PALAMIX®** vacuum mixing system, **pro mixing system**. **PALAGUN®** is used exclusively in combination with the products named.

2. Package contents and composition

One **PALAGUN®** set contains:

- 1 **PALAGUN®** system including a locking cover
- 1 instructions for use

PALAGUN® is double packed. The outer bubble pouch is for transportation purpose only and therefore unsterile. Inside this outer pouch is an inner pouch that is unsterile from the outside and sterile from the inside. This inner pouch contains the set.

All components of the **PALAGUN®** are made of medical-grade plastic and are latex-free and PVC-free. The product does not contain any critical substances such as phthalates, plasticisers, allergenic substances or potentially carcinogenic substances.

3. Indications

PALAGUN® is intended to accommodate mixing cartridges to ensure precise and effortless application of the bone cement. The mixing cartridges of the following products can be used: **PALAMIX®** vacuum mixing system, **pro mixing system**.

4. Contraindications and restrictions on use

PALAGUN® is used exclusively in combination with the products named under the indications. Other mixing cartridges are not compatible.

5. Side effects

There are no side effects associated with **PALAGUN®**.

6. Interactions

There are no interactions associated with **PALAGUN®**.

7. Warnings, precautions and relevant information

User

Before using **PALAGUN®**, the user should be well-acquainted with its properties and handling. We recommend that users practise the complete procedure before using it for the first time. The user must also be familiar with the bone cement and the mixing and application system used. The instructions for use for all the products used must be noted beforehand.

PALAGUN® may only be used if it is undamaged.

8. Handling

General information

PALAGUN® is intended for single use and must not be reused or resterilised.

The **PALAGUN®** should only be used by trained personnel. There is a risk of hand injury or damage to the protective glove if the device is not handled properly. The particular mixing cartridge used may also be damaged such that the bone cement application may be hampered or impossible.

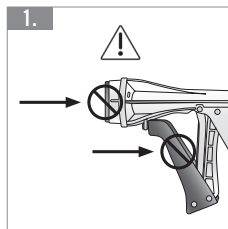
Opening

The pouch must only be opened under sterile conditions. For this purpose, the inner pouch is available sterile after the removal of the outer pouch. If the sterile barrier is damaged, the **PALAGUN®** must not be used and must be disposed of.

Preparation

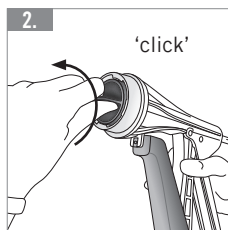
Before using the **PALAGUN®**, it should be checked for any damage and completeness.

Use

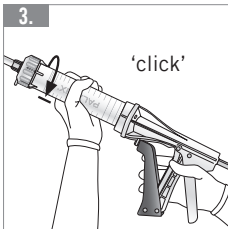


Important:

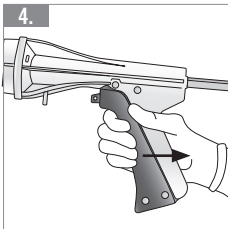
Do not remove the locking cover or squeeze the trigger prior to assembly of cartridge for use.



When ready to assemble cartridge and use, turn the locking cover counterclockwise until released and then remove it. Do not squeeze trigger yet.



Attach the mixing cartridge of the products named under the indication onto the **PALAGUN®** until a 'click' is heard.



The trigger of the **PALAGUN®** bone cement gun is operated by hand to expel the bone cement from the cartridge. Activating the trigger pushes forward the feed rod in the mixing cartridge and expels the bone cement under high pressure.

Anomalies

PALAGUN® should not be used if the packaging is damaged.

The product should also not be used if any product components are damaged or missing.

Incompatibilities

None known based on current knowledge.

Disposal

PALAGUN® and the outer packaging can be disposed of in normal hospital waste. Please comply with local environmental legislation and waste disposal regulations.

9. Storage

PALAGUN® must be stored unopened in a dry and clean place in the original packaging.

10. Shelf-life

The expiry date is shown on the outer pouch. **PALAGUN®** must not be used after the specified expiry date has passed.

11. Sterility

PALAGUN® is sterile and was sterilised with ethylene oxide (EO) gas.

The contents of unused, opened or damaged packs must not be resterilised and must be discarded.

PALAGUN® is intended for single use and must not be reused or resterilised because the product quality will be negatively affected by repeat sterilisation.

Symbols



Manufacturer



Catalogue number



Consult instructions for use



Batch code (Lot number)



Sterilized using ethylene oxide



Do not use if the product sterile barrier system or its packaging is compromised



Do not re-use



Do not re-sterilize



Use by date



Keep dry



Federal law U.S.A. restricts this device to sale, distribution, and use by or on the order of a physician

CL006-02-INE(Z) / Rev.: B

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