

INSTRUCTION

Handling of Sterile Plates, Screws, Staples and Instruments



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For further information regarding the Medartis product lines, please visit www.medartis.com

Introduction

Medartis products are now also available sterilized and ready for use offering several benefits to the surgeon and the hospital.

Sterilized implants eliminate:

- Risks of reprocessing
- Costs of cleaning and disinfecting
- Cost of sterilization



Blister type packaging with labels, tube, blister and cardboard box

Packaging Concept

Medartis products are packaged either as blister packaging or as pouch packaging:

Blister Type Packaging

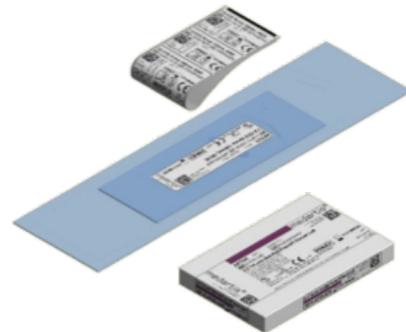
- Blister type sterile barrier packaging containing an injection molded, laser welded Styrene Methyl Methacrylate (SMMA) tube with metal inserts for product storage
- Used for screws, short K-wires and short twist drills



Inner injection molded tube

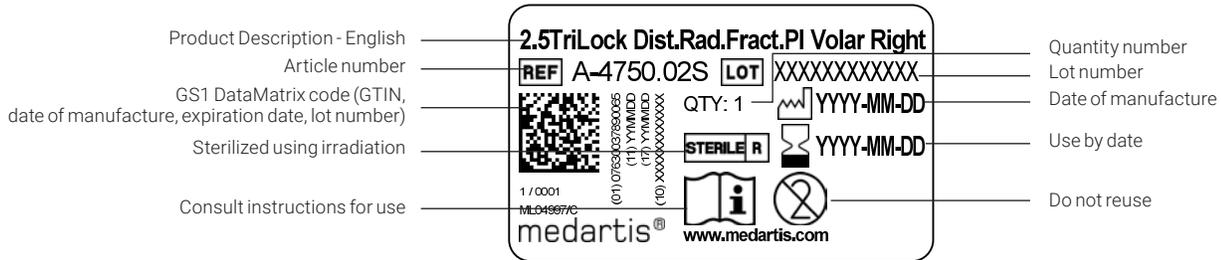
Pouch Type Packaging

- Pouch type packaging with heat sealed PA / PE pouches
- Used for plates, staples, long K-wires, long twist drills and reamers



Pouch type packaging with labels, sealed pouches and cardboard box

Patient Label Overview



Sterilization Method

Medartis sterile plates, screws, staples and instruments undergo an irradiation sterilization process. The sterile barrier packaging consists of an outer sealed blister packaging

containing a tube for product storage, or an outer pouch containing an inner pouch for enhanced handling and safe transport of the product.

Handling Instructions

Prior to Use

- Check the use by date.
- Inspect and verify the physical integrity of the packaging and do not use any product where the sterile packaging has been opened or damaged.
- Confirm contents are per surgeon's request.

Warning

Do not use sterile products after the expiration date.

Notice

Once the sterile packaging has been opened, the product cannot be resterilized.

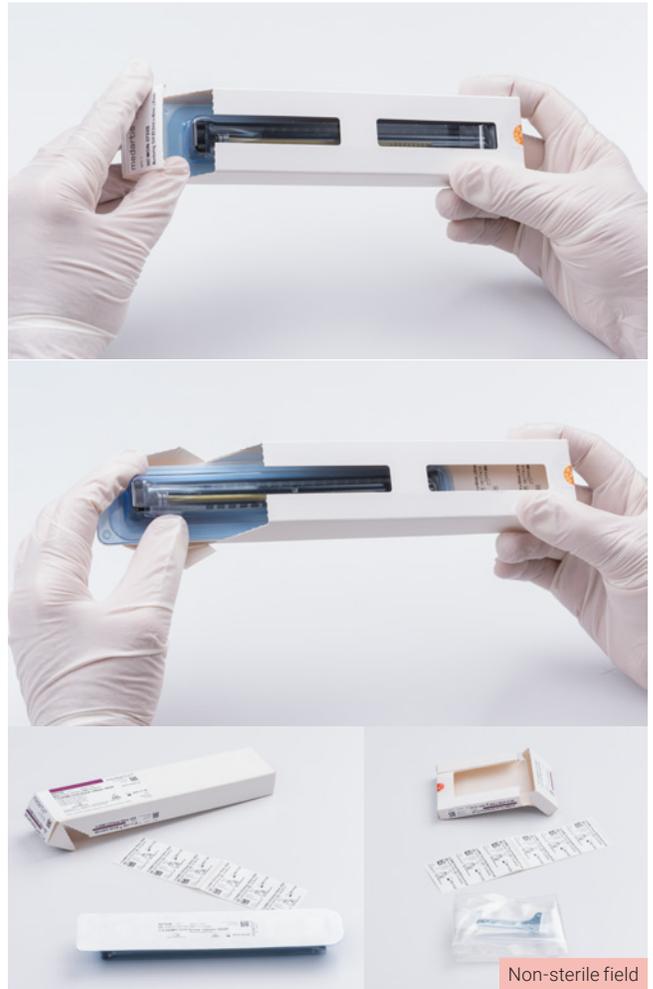
Devices are for single use only and may not be reused or resterilized under any circumstances.



Opening Sterile Packagings

Example: Blister and tube combination

- Sterile products should be opened aseptically following specific guidelines.
- Circulating nurse in the non-sterile field
 - Break the seal of the exterior box at the serrations and remove the contents.
 - Position the contents of the packaging outside the sterile field on a flat dry surface.
 - Check the physical integrity of the outer blister packaging and do not use if opened or damaged.



Opening the Outer Packaging

- Circulating nurse in the non-sterile field
 - Open the blister packaging by peeling back the lid foil and folding the upper part down by a maximum of two thirds.
 - Make sure that there is no contact between the opened lid and the inner rim or any part of the inner blister.



Removing the Inner Tube or Inner Pouch

Inner Tube

- Circulating nurse in the non-sterile field
 - Hold the peeled back lid with your thumb and place the index finger in the channel of the blister.
 - Hold the front and bottom of the blister packaging with the other hand.
 - Slowly press the blister upwards with the index finger resting in the channel, while holding the back of the tube with the thumb. The tube, which is still covered with the sterile peeled back lid, will tilt upwards.



- Scrub nurse in the sterile field
 - Remove the inner tube in the sterile field while maintaining the sterility and integrity of the product.
 - Care must be taken that the tube does not touch any part of the packaging that is not sterile.



Inner Pouch

- Circulating nurse in the non-sterile field
 - Open the outer pouch with two hands and present the inner pouch to the scrub nurse in the sterile field.

Notice

Sterile products should never be dropped onto a sterile field as they may roll off the edge, create a hole in the sterile drape, or cause other items to be displaced, leading to contamination of the sterile field.



- Scrub nurse in the sterile field
 - Carefully remove the inner pouch and make sure that it does not touch any non-sterile part of the packaging.

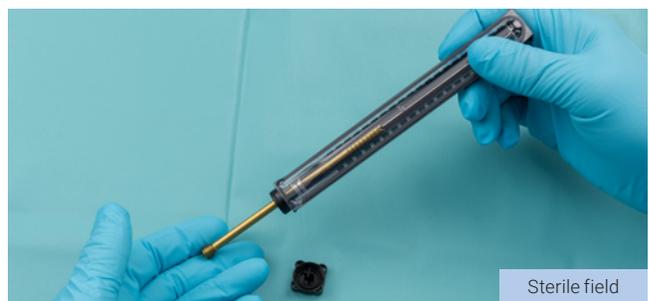
Removing the Contents of Inner Pouch or Tube

- Scrub nurse in the sterile field
 - Open the inner pouch over the sterile field with two hands.
 - The contents of the inner pouch are removed and placed on a flat surface in the sterile field.



Screw Pick-Up

- Scrub nurse in the sterile field
 - Hold the tube upright and open the inner tube by removing the cap.
 - Insert the screwdriver vertically into the screw head of the screw in the tube and pick up the screw with axial pressure.
 - Remove the screw from the tube. If necessary, hold the screw with the finger to the screwdriver blade.
- Alternative method
 - Remove the screw by gently tilting the tube and sliding the contents onto the flat surface in the sterile field.



Recording of Lot and Implant Information

- Circulating nurse in the non-sterile field
 - Place the patient labels of the used implants in the patient's record to improve batch identification and traceability and to ensure accurate hospital documentation of implant use.

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