

medartis

PRECISION IN FIXATION

INSTRUCTION

Handling of Sterile Plates, Screws, Staples and Instruments



APTUS MODUS

Contents

3	Introduction
4	Patient Label Overview
4	Sterilization Method
4	Handling Instructions
4	Prior to Use
5	Step by Step Opening of Sterile Packages
5	Opening the Outer Packaging
6	Removing the Inner Tube or Inner Pouch
7	Removing Contents of Inner Pouch or Tube
7	Screw Pick-Up
7	Recording of Lot and Implant Information

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, tubes, blister and cardboard box

Packaging Concept

Medartis products are packaged in either of the two packaging types:

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

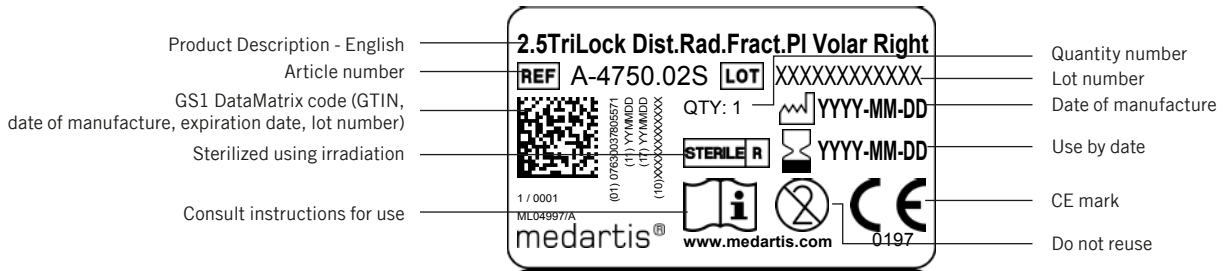
Pouch Type Packaging

- 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 package

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.

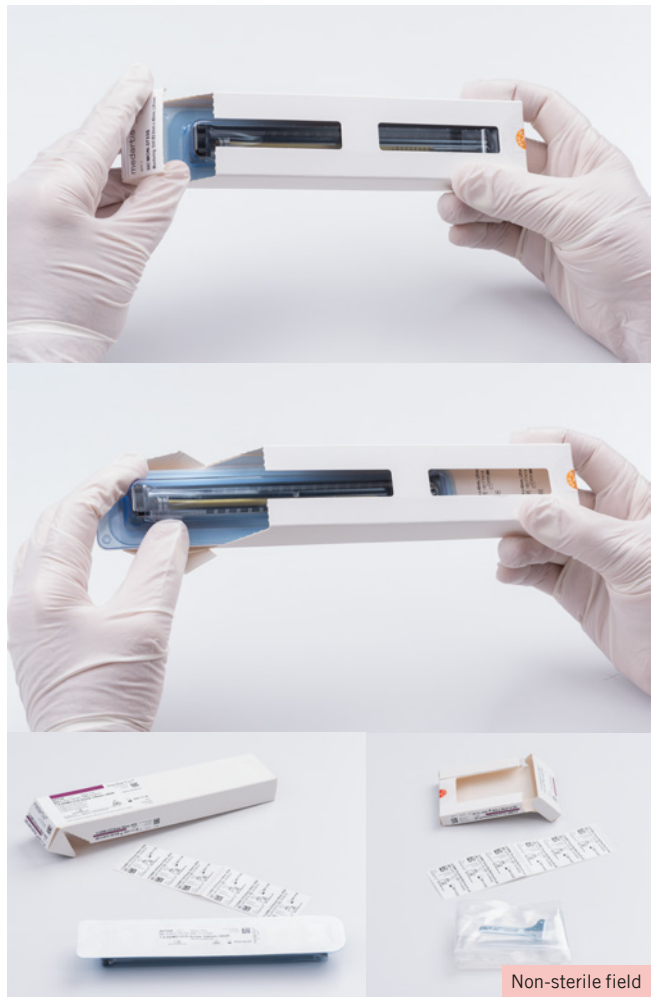
Devices are for single use only and may not be reused or resterilized under any circumstances.



Step by Step Opening of Sterile Packages

Example: Blister and tube combination

- Sterile items 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 package contents 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 pack by peeling back and folding the top half to 2/3 of the way down
 - Make sure 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 back the peeled back lid with thumb, place trigger finger in channel of blister
 - Hold front and bottom of blister pack with second hand
 - Bend blister slowly upwards with trigger finger in channel, while holding the back of the tube with the thumb. The tube which is still covered by the sterile peeled back lid, will tilt upwards



- Scrub nurse in sterile field
 - Scrub nurse to remove the inner tube in the sterile field maintaining item sterility and integrity
 - 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 articles 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 sterile field
 - Scrub nurse to remove the inner pouch with care ensuring there is no contact with any part of the packaging that is not sterile

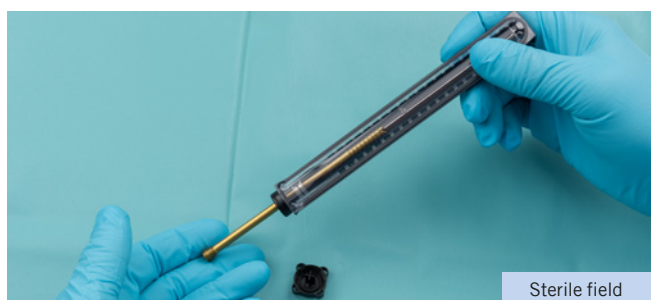
Removing Contents of Inner Pouch or Tube

- Scrub nurse in sterile field
 - Scrub nurse to open the inner pouch over the sterile field with two hands
 - Contents of the inner pouch are to be removed and placed onto a flat surface in the sterile field



Screw Pick-Up

- Scrub nurse in sterile field
 - Hold tube upright and open the inner tube by removing the cap
 - Insert screwdriver vertically into screw head of the screw in the tube and pick up the screw with axial pressure
 - Remove screw from the tube. If necessary, hold screw on screwdriver blade with finger
- Alternative method
 - Remove screw by gently tilting tube and sliding out 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 from the used implants in the patients file to enhance lot identification and tracking, as well as achieve accurate hospital documentation of implant utilization

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