

INSTRUCTIONS FOR USE (IFU) - STERILE BARRIER SYSTEMS

Paper/Film Bags-Reels ■ Tyvek®/Film Bags-Reels ■ Non-woven (TNT)/Film Bags ■ Crepe Paper Sheets
For Sterilisation Processes

Medical Device (MD) Class I – Non-invasive product (non-sterile)

1. PRODUCT NAME AND INTENDED PURPOSE

This document contains the instructions for use for the Sterile Barrier Systems (SBS) of **Bolsaplast** in accordance with **Regulation (EU) 2017/745 (MDR) - Annex I - Section 23.4**

Model/Code	Materials	Sterilisation methods	Sealing conditions
Paper/Film Bag (flat, gusseted, self-seal) Paper/Film Reel (flat, gusseted) (MBO-MBF-MBA-MRP-MRF)	Medical Grade Paper + PET/PP Laminate	Steam / Ethylene Oxide / Formaldehyde / Gamma	170°C - 210°C (Heat sealing) Not applicable to self-seal
Tyvek®/Film Bag (flat, self-seal) Tyvek®/Film Reel (flat) (MBT-MBTA-MRT)	Tyvek® + PET/PE Laminate	Plasma VH ₂ O ₂ / Ethylene Oxide / Gamma	120°C - 130°C (Heat sealing) Not applicable to self-seal
Non-woven (TNT)/Film Bag (flat) MBCOVER	Non-woven Fabric (TNT) + PET/PP Laminate	Steam / Ethylene Oxide / Formaldehyde	160°C - 165°C (Heat sealing)
Crepe Paper Sheets (MCREPV)	Medical Grade Cellulose	Steam / Ethylene Oxide / Formaldehyde	Manual wrap + adhesive tape

2. INSTRUCTIONS FOR USE AND HANDLING

1. Selection and filling: select the appropriate size for the product to be sterilised. The product being sterilised must not occupy more than 3/4 (75%) of the usable volume of the bag or reel, to avoid stress on the seals and prevent tearing during the process. Likewise, packages must not be overloaded, to avoid tearing caused by excessive weight

2. Loading the product: insert the product to be sterilised, clean, disinfected and dry, taking care as you do so. Make sure not to force the edges or pierce the material with sharp points. For crepe paper sheets, generally position the material diagonally in the centre of the sheet and place the indicator or internal chemical integrator at the centre of the package. Follow the folding procedure established for each case.

3. Sealing the package: when heat-sealable, set the heat-sealing machine to the temperature recommended for the material (see sealing conditions in section 1). For self-seal bags, remove the protective strip, fold along the marked line and press from the centre towards the edges, avoiding creases or air pockets. It is very important to close self-seal bags correctly and to take the time needed to do so. For crepe paper sheets, seal the package with the adhesive indicator tape for the relevant sterilisation process

4. Placement in the steriliser: place the bags and packages following your facility's protocol, usually with the plastic side facing the plastic side and the paper side facing the paper side. The use of separating trays is recommended to optimise circulation of the sterilising agent. It is recommended not to pack the packages tightly in the steriliser. Leaving space ensures better penetration of the sterilising fluid and reduces risks

5. Completion and drying: check that the packages are completely dry before removing them from the steriliser. A damp package increases the risk of tearing and puts the bacterial barrier function at risk. Remove the product from the steriliser once it is dry and cool

3. STORAGE CONDITIONS AND SHELF LIFE

Store products in their original packaging in a cool, dry place protected from direct sunlight, heat sources and chemicals (acids/bases). In the case of Tyvek materials® with a chemical indicator of VH_2O_2 , it is additionally recommended to keep it away from the steriliser throughout the process and, when not in use, to cover it with an opaque, dark plastic that blocks out light. The shelf life shown in the table below corresponds to optimal storage and use conditions:

Model/Code	Shelf life	Sterility test
Paper/Film Bag (flat, gusseted, self-seal) Paper/Film Reel (flat, gusseted) (MBO-MBF-MBA-MRP-MRF)	4 years from manufacture	Up to 365 days (Tests: ISO 11737-2 / ASTM F1929 / ASTM D 903-93)
Tyvek®/Film Bag (flat, self-seal) Tyvek®/Film Reel (flat) (MBT-MBTA-MRT)	3 years from manufacture	Up to 365 days (Tests: ISO 11737-2 / ASTM F1929 / ASTM D 903-93)
Non-woven (TNT)/Film Bag (flat) MBCOVER	4 years from manufacture	Up to 365 days (Tests: ISO 11737-2 / ASTM F1929 / ASTM D 903-93)
Crepe Paper Sheets (MCREPV)	5 years from manufacture	Up to 180 days (Tests: ISO 11737-2)

Recommended storage conditions: Temperature -20°C to 45°C | Relative Humidity 0%–80%

4. CHEMICAL INDICATORS AND WARNINGS (MDR 2017/745)

• **Process Indicators:** the printed chemical indicators change colour after exposure to the corresponding sterilisation process. **IMPORTANT: The chemical indicator is a process indicator only and does NOT confirm the sterility of the product.** It must be combined with biological indicators to validate the effectiveness of the cycle

SAFETY WARNINGS AND RESIDUAL RISKS:

1. SINGLE-USE PRODUCT (Do not reuse): Reusing this packaging carries a risk of loss of sterility, cross-contamination and failure of the barrier system
2. DO NOT USE IF THE PACKAGING IS DAMAGED OR TORN

5. GUIDE TO SYMBOLS USED ON THE LABELLING (ISO 15223-1)

The symbols used on the labelling of the products indicated, and their meaning, are detailed below:

Symbol / Code	Official Name	Meaning and Explanation of Use
REF	Catalogue Number	Indicates the manufacturer's reference for identifying the product
LOT	Batch Code	Indicates the manufacturing batch for product traceability
	Manufacturing Date	Indicates the date on which the product was manufactured
	Expiry Date	Indicates the deadline after which the product must not be used
MD	Medical Device Medical Device	Certifies that the product is a Medical Device under Regulation (EU) 2017/745
CE	CE Marking	Indicates that the product complies with European Union legal requirements
UDI	Unique Device Identifier	Global numeric code that uniquely identifies the product
	Non-sterile	Indicates that the product is supplied non-sterile
	Do Not Reuse / Single Use	Indicates that the product is for single use. Do not re-sterilise or reuse
	Do not use if the packaging is damaged	Indicates that the product must not be used if the packaging is open or damaged
	Protect from Sunlight	Indicates that the product must be kept away from sunlight and heat sources
	Keep dry	Indicates that the product must be protected from moisture and stored in a dry environment
	Humidity Limit	Indicates the appropriate relative humidity range for storing the product (0%-80%)
	Temperature Limits	Indicates the appropriate temperature range for storing the product (-20°C to +45°C)

6. MANUFACTURER DETAILS AND CONTACT

BOLSAPLAST, S.L.

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Registered in the Barcelona Companies Register, Volume 22044, Folio 195, Sheet B 32222.

INSTRUCTIONS FOR USE (IFU) – ACCESSORY PRODUCTS NOT STERILE BARRIER SYSTEMS

Bags ■ Adhesive Tape

1. PRODUCT NAME AND CHARACTERISTICS

Accessory products used in packaging, storage, transport or material-handling processes, which are not a Sterile Barrier System (SBS)

Model/Code	Materials	Shelf life	Sealing/Closure Conditions
Transparent plastic bag (MBDUST)	PE	5 years from manufacture	Adhesive tape
Red or yellow biohazard bag (93534)	PP	4 years from manufacture	With a cable tie, leaving space for the sterilising fluid to enter
Bag with windows (MBPOCKET)	Non-woven Fabric (TNT) + PET/PP Laminate	4 years from manufacture	Not closed or sealed
Steam adhesive tape (MCV)	Cellulose + adhesive	2 years from manufacture	Not applicable

Recommended storage conditions: Temperature -20°C to 45°C | Relative Humidity 0%–80%

2. INSTRUCTIONS FOR USE AND HANDLING

1. MBDUST: insert the products, already sterile in their original packaging, inside this bag. As a recommendation, the product placed inside the bag should be less than 3/4 (75%) of the bag's usable volume. Separate the protective strip from the adhesive band, fold it inwards and press firmly from the centre outwards, avoiding creases or air pockets in the seal. Write any information you consider useful in the blank box printed on the bag. Proceed to store the bag

2. 93534: insert products to be sterilised inside the bag, carefully and avoiding sudden impacts. The bag must not be closed by heat sealing or by mechanical means. Use a cable tie to close the bag, leaving enough space for the sterilising fluid to penetrate. This material is sensitive to low temperatures, so whenever the temperature is below 0°C (whether in storage or transport) it is recommended that the bag be conditioned/brought to temperature before use, for at least 24 hours at temperatures between 10°C-30°C

3. MBPOCKET: insert the products to be sterilised one by one or in groups of the same type, into each of the bag's dividers (windows). Roll up the bag to save space or place the flat bag directly into a metal container or into a bag or package (sterile barrier for the sterilisation process). Seal the bag or close the container as instructed by the manufacturer of the bag or container

4. MCV: cut the tape to the desired length and place it over the area to be sealed. Cut and apply each individual unit according to the use required. A dispenser is usually used to cut the tape and make the process easier. If a dispenser is not available, use mechanical means to cut it (scissors, cutter, etc.)

3. GUIDE TO SYMBOLS USED ON THE LABELLING (ISO 15223-1)

The symbols used on the labelling of the products indicated, and their meaning, are detailed below:

Symbol / Code	Official Name	Meaning and Explanation of Use
REF	Catalogue Number	Indicates the manufacturer's reference for identifying the product
LOT	Batch Code	Indicates the manufacturing batch for product traceability
	Manufacturing Date	Indicates the date on which the product was manufactured
	Expiry Date	Indicates the deadline after which the product must not be used
	Non-sterile	Indicates that the product is supplied non-sterile
	Do Not Reuse / Single Use	Indicates that the product is for single use. Do not re-sterilise or reuse
	Do not use if the packaging is damaged	Indicates that the product must not be used if the packaging is open or damaged
	Protect from Sunlight	Indicates that the product must be kept away from sunlight and heat sources
	Keep dry	Indicates that the product must be protected from moisture and stored in a dry environment
	Humidity Limit	Indicates the appropriate relative humidity range for storing the product (0%-80%)
	Temperature Limits	Indicates the appropriate temperature range for storing the product (-20°C to +45°C)

4. MANUFACTURER DETAILS AND CONTACT

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