



**CONTINUOUS LINERS,
& SPECIAL BAGS**

GMP
MANUFACTURING

GMP MANUFACTURING IN CLEAN ROOM ENVIRONMENT

Our activity started with the **CONTINUOUS LINER MANUFACTURING**.

These Donuts are made of plastic material which is wound, compressed, and pre-packaged in order to obtain several meters of material which may be applied on discharge or transfer pipes, occupying the lowest amount of space. The **CONTINUOUS LINER**, packed in this way, allows to obtain cylindrical volumes (*drum liner*) which may be then unwound or unrolled from the Donut into the drum, making it possible to load dusty material avoiding any contact with the drum itself (*packaging*).

Most of all, the **CONTINUOUS LINER** makes it possible to **never open the discharge circuit**, replacing a drum with the following one during discharge/transfer phases, which usually require several containers.

An **extreme versatility** which allows the creation of several solutions in different shapes and colors, even specific ones, thus favouring the realization of **FLEXIBLE ISOLATORS** to confine all the **exposed** operations. Sometimes called **GLOVE BAGS** are similar to plastic bubbles equipped with gloves, filters, usually put into place as **AD HOC solutions for specific needs**, assessing which atmospheres must be sealed and molding the shapes which may be ergonomically more appropriate in order to allow for the best use by the operators.

The scope of our applications (*chemical-pharmaceutical*), has inevitably pushed us to increase the quality of our internal manufacturing capacity and quality, in terms of control and tracking of the production processes and supplied products as well as the environments in which the production, packaging and storage operations are carried out, in accordance to specific pharmaceutical requirements (**GMP** or **Good Manufacturing Practice**) and quality standard (**ISO 9001: 2015**)

This development has led to a radical transformation of the **MANUFACTURING FACILITY** towards an **ISO 7 and 8 classification**, using **areas with controlled atmosphere, filtered air, differential pressures cascade, clean room particle monitoring, separate material and personnel flows**.

In summary, environments, production processes, process controls and materials had to comply with the quality requirements indicated by pharmaceutical rules and practise as well as our customers requirements. Indeed, our customers have led the development of this process by suggesting the improvements needed to become a **Qualified flexible technology supplier**.

Our production process involves the use of basic material (low density polyethylene) directly supplied by CSV, rigorously certified and accompanied by the documentation required by the pharmaceutical industry. Furthermore, we can also **transform material provided by third parties or other suppliers** indicated by the final customers, **especially** in case **stability studies have already been carried out**. All of this, with the purpose to speeding up the production of the items required, without compromising the quality assessment on the **material already validated** by our customers.

The presence and use of qualified **automated heat-sealing equipment** allows a **RELIABLE and HIGH QUALITY MANUFACTURING** of **several designs of liners and flexible isolators**.

Given that our work can be considered as a form of **industrial tailoring**, we have **the habit of involving our final customers in the definition of the shape which they may like and need**, in order to ease the use of the devices, make their installation simple and their decontamination, removal or replacement quicker.



DONUT Continuous LINER

PRO:

- Simply to be installed by a unique operator thanks to the encapsulated oring and the prepacked donut format
- Very easy and fast to use and changed

CONS:

- Size and shape suitable for installation onto pipe but critical to transfer into a Glove Box Via Rapid Transfer Port having a limited diameter
- Space consuming during shipment



AVAILABLE standard MODELS

- DIAMETER: 4", 6", 8", 14", 16", 18", 21", 23"
- LENGTH: 3, 5, 7, 10, 15, 20, 25, 30, 45m
- THICKNESS: 60, 70, 80, 90, 100, 120, 150 MICRON
- CUSTOM MADE WITHOUT LIMITS

APPLICATIONS

- PRODUCT/POWDER CONTAINED OFFLOADING/DISCHARGE BY GRAVITY
- PRODUCT CONTAINED SAMPLING
- SAMPLES TRANSFER AND BAG OUT
- REJECTED TRANSFER AND BAG OUT
- ISOLATOR/GLOVE BOXES BAG OUT
- ISOLATOR/GLOVE BOXES BAG IN
- FLOW HOODS BAG IN/OUT INTERFACE
- CRIMPS/CAPS CONTAINED TRANSFER PORT

MATERIALS

- EU & US PH COMPLIANT
- ANTISTATIC LDPE
- ANTISTATIC LLDPE
- ATOSSIC LDPE
- ATOSSIC LLDPE

COLORS

- FULLY TRANSPARENT
- TRANSPARENT BLUE
- TRANSPARENT GREEN
- BLACK

FOLDED Continuous LINER

PRO:

- Size and shape suitable to transfer into a Glove Box Via Rapid Transfer Port having a limited diameter
- Reduced stock space and delivery costs due to the compressed and collapsed folded format

CONS:

- Difficult to be installed by a unique operator without a support device



AVAILABLE standard MODELS

- DIAMETER: 4", 6", 8", 14", 16", 18", 21", 23"
- LENGTH: 3, 5, 7, 10, 15, 20, 25, 30, 45m
- THICKNESS: 60, 70, 80, 90, 100, 120, MICRON
- CUSTOM MADE WITHOUT LIMITS

APPLICATIONS

- PRODUCT/POWDER CONTAINED OFFLOADING/DISCHARGE BY GRAVITY, VIA PIPE, INTO DRUMS/CONTAINERS
- PRODUCT CONTAINED SAMPLING
- SAMPLES TRANSFER AND BAG OUT
- REJECTED TRANSFER AND BAG OUT
- SOLATOR/GLOVE BOXES BAG OUT
- ISOLATOR/GLOVE BOXES BAG IN
- FLOW HOODS BAG IN/OUT INTERFACE
- CRIMPS/CAPS CONTAINED TRANSFER PORT

MATERIALS

- EU & US PH COMPLIANT
- ANTISTATIC LDPE
- ANTISTATIC LLDPE
- ATOSSIC LDPE
- ATOSSIC LLDPE
- LDPE AND LLDPE FOR PHOTOSENSITIVE APPLICATIONS

COLORS

- FULLY TRANSPARENT
- TRANSPARENT BLUE
- TRANSPARENT GREEN
- BLACK

DRUM LINERS & SPECIAL BAGS



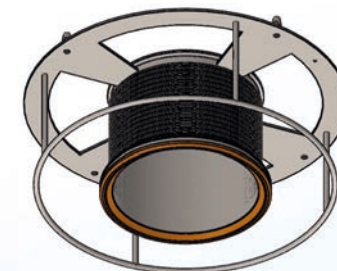
MATERIALS

- EU & US PH COMPLIANT
- THICKNESS: 150 MICRON MINIMUM
- ANTISTATIC LDPE
- ANTISTATIC LLDPE
- ATOSSIC LDPE
- ATOSSIC LLDPE

APPLICATIONS

- EQUIPMENT COVERAGE TO MINIMIZE CONTAMINATION
- SURFACE COVERAGE TO AVOID PRODUCT CONTACT AND DECONTAMINATION/CLEANING NEEDS
- SPECIAL TRANSFER SLEEVES
- SPECIAL FLEXIBLE CONTAINER
- PRE SHAPED DRUMS LINER

CONTINUOUS LINER HARDWARE CANISTER



AVAILABLE standard MODELS

- STANDARD DIAMETER:
- 3", 4", 6", 8", 12", 14", 16", 18", 23"
- STANDARD LENGTH:
- 10, 15, 20, 25, 35, 40m
- DIFFERENT CUSTOM MADE SIZE ON REQUEST

APPLICATIONS

- SUPPORT SYSTEMS FOR CONTINUOUS LINER USAGE
- OFFLOADING
- SAMPLING
- BAG IN/OUT

MATERIALS

- AISI 304 AISI 316L STAINLESS STEEL MADE
- ALLOY C22
- PTFE WHITE
- PTFE CONDUCTIVE BLACK
- HDPE WHITE
- HDPE CONDUCTIVE BLACK
- POM WHITE
- CUSTOM MADE WITH ANY OTHER METALPLASTIC MATERIALS
- METAL ANTIACID TREATMENT



Build Different

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