Technical characteristics



The BCS port is made of thermoplastic polyester PBT which is class VI ISP 23 biocompatible

PBT is compliant with the FDA requirements (CFR, Title 21, Part 177, Section 1660):

- The PBT is suitable for sterilisation through autoclaving and gamma or beta radiation.
- No significant development was observed in the breaking strength between PBT Celanex 2402 MT without sterilisation and with sterilisation through autoclaving or gamma radiation.
- The breaking strength of the material reduces at the most by 5% after 3 gamma radiation procedures.
- Very high resistance to ionising radiations.

Excellent resistance of PBT to different sterilisation agents and systems in the market (autoclave, gamma and beta radiation, hydrogen peroxide, IPA):

- The traction and impact tests show that the mechanical properties of the PBT change at the most by 3%.
- Isopropyl alcohol or hydrogen peroxide do not affect the weathering

The D-value of the PBT is 1.20 min (this value allows measuring the time required to kill 90 % of the bacteria on a coupon).

The joint encapsulated in the thermoplastic elastomer SEBS (Thermolast M) is compliant with the FDA requirements (CFR, Title 21, Part 178,



ANY QUESTIONS, NEED FURTHER INFORMATION?

Please do not hesitate to call us or write to us, Piercan is at your disposal for your

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- **E-mail** piercan@piercan.fr

THE PIERCAN SOLUTION

The BCS glove port is available for different models of gloves and safety sleeves.

Choice of material for the gloves





· Excellent resistance to chemical products and sterilising agents





- FDA approved material
- · High resistance to sterilisation





cytotoxic products





POLYURÉTHANE/CSM

- Extremely resistant elastomer
- · Flexibility and dexterity
- Choice of material for the safety sleeves





· Excellent resistance to chemical products and sterilising agents





- FDA approved material
- High resistance to sterilisation





High levels of protection against cytotoxic products





tremely resistant elastomer exibility and dexterity





Mechanical resistance

• Options for decontamination and sterilisation

CLASS 200 PARTICULATE DECONTAMINATION

The validation of the particulate decontamination of the port has been done as per the standard IEST-STD-C-1246D. The application of the PIERCAN standard for the particulate decontamination of the glove with its port and the safety sleeve with its port, is in compliance with the class 200 requirement.

GAMMA RADIATION STERILISATION

The validation of the port sterilisation was carried out as per the VDmax25 method in compliance with the standards NF EN ISO 11137 and 11737.





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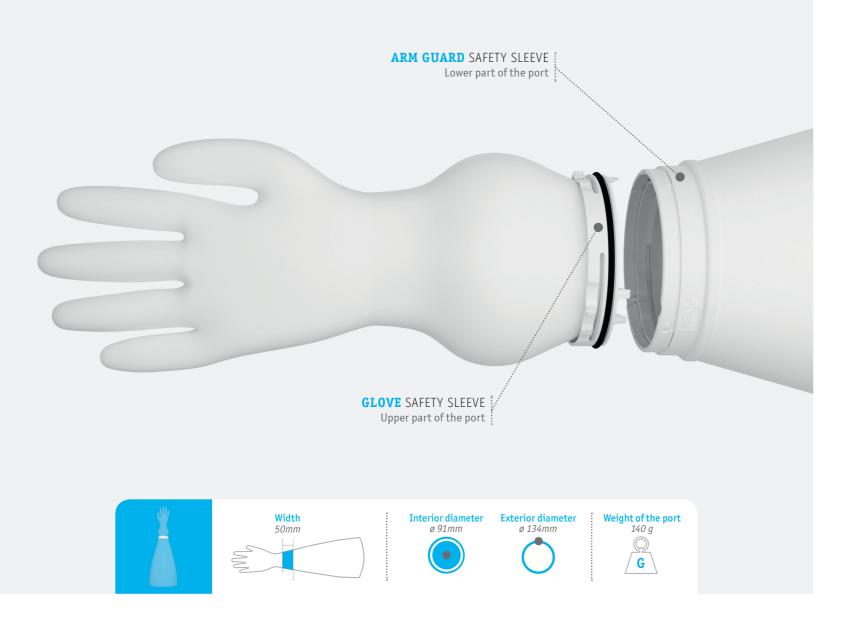




The glove port BCS Piercan

Secure your containment and remain connected





The BCS Piercan glove port

The gloves in the PIERCAN glove box protect the operators and products from irreversible risks. When gloves mounted in ports are changed several times, the manipulations are often delicate, complex, and long. With its new securised glove port, PIERCAN is offering an innovative and high-performance solution which will simplify and securised operations.



PIERCAN offers a patented and innovative solution, developed by its research and development laboratory: the securised glove port (BCS, bague de connexion sécurisée) that allows changing gloves without loss of containment.

Reminder of the classic problems related to fixing:

- The complex nature of the change process involves a risk of loss of containment
- The strength required in the fingers may cause MSD (musculoskeletal disorders)
- Only 5% of operators are authorised to change the gloves using traditional methods
- Despite specialised training, the operators are not convinced about the effectiveness of the current systems
- There is a risk of micro-tears on the glove near the glove ring
- There is a risk of it dislodging during the manipulation operations

The securised glove ports (BCS) resolves these problems and facilitates the operators' work.

Simple and quick change

The ease of use ensures that any used can change the gloves without loss of containment, in a very short time, without effort, while retaining the safety sleeve.









1 • Insert the glove to be chan-

2 • Position the 3 clips of the new glove opposite the grooves, thumb facing upwards (2 arrows on the upper side of the glove thumb).



ged inside the safety sleeve.





4 • Lock the port by pressing on the 3 clips



5 • The used glove is ejected inside or outside the isolator.

PRODUCT BENEFITS

• Extremely reduced efforts

Changing the port requires a force of 70 N to install the glove and 110 N to remove it. This reduced force allows any user to change the gloves in an isolator or "RABS closed doors" and avoids the risk of musculoskeletal

Simplified training and authorisation of the personnel

The simplicity of changing the glove significantly reduces training time. PIERCAN recommends changing the gloves on an isolator or school RABS, by verifying that the 3 studs of the glove port are properly positioned in the 3 slots provided for this purpose.

Increased endurance

After 20 glove port changes, the mechanical strength of the glove safety sleeve body in the arm guard safety sleeve is not altered.

Two methods of changing the glove

The change may be carried out through over-pressure (removing the glove towards the exterior), and also by under-pressure (removing the glove towards the interior of the isolator).

The BCS glove port, triple security

The risk of loss of containment is significantly reduced owing to the mechanical strength of the glove-port-safety sleeve assembly as regards the sealing obtained and the protection of the glove during operations and changing.

MECHANICAL STRENGTH

All the components of the port possess a mechanical strength 4 times higher than the EN 421



- The port prevents the gloves from coming loose.
- It cannot be removed without another glove port or a cover port, which prevents untimely

ENSURING INTEGRITY

The BCS port is in accordance with the standard EN 421 confirmed through a bacterial test which demonstrates the sealing level of the port over 5

- The test consists of inoculating a suspension of Brevundimonas diminuta (concentration higher than 106 UGF/ml) at the lip seal, inside the safety sleeve, with a pressure of 50 Pa in the isolator. After 5 changes, the test demonstrates the absence of microbial growth between the body of the glove safety sleeve and the body of the arm guard safely sleeve near the lip seal.
- As long as the old glove is not removed, the lip

PROTECTION OF THE GLOVE

The BCS port protects the glove at the wrist. This assembly avoids cuts because the zone is no longer stretched and remains protected by the safety



seal of its port ensures containment.