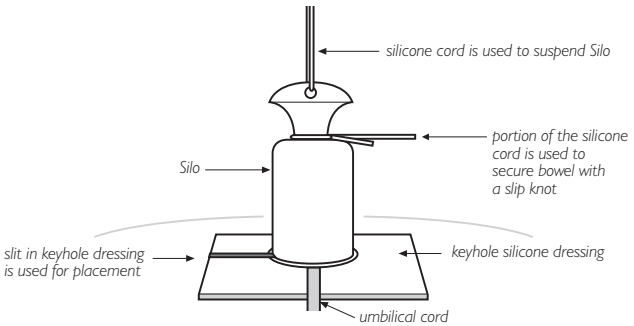
The medicina silo

Instructions for Use

- *Medicina's Silos are pre-formed silicone bags indicated for use in neonates with gastroschisis for bedside staged closure or as a temporary protection before traditional theatre closure.*
- **The Silos are for use by healthcare professionals only, in a clinical setting**
- **Not to be used if the neonate becomes haemodynamically unstable or cannot tolerate the procedure. Only when stable can the procedure be recommenced or consider closure under general anaesthesia.**
- **Careful haemostasis is important to prevent postoperative haematoma formation. If bleeding persists the device should be removed.**
- **It is important to maintain adequate gut perfusion, therefore careful and frequent inspection of the bowel colour should be made. If doubt exists, incision of the fascial ring in the 12 o'clock position or removal should be considered.**
- **It is recommended that the patient is monitored for obstruction of the inferior vena cava and any compromise of the ventilation due to elevation of the diaphragm; both of which may be caused by raised intra-abdominal pressure from the introduction of the viscera.**

The Silo provides a closed environment for containment of exposed intestine. A Silo can be placed soon after birth without need for general anaesthesia. The aim is to reduce the leakage of serous exudate, reduce heat loss, stabilise the gut for transfer, reduce the risk of torsion and facilitate the abdominal repair. The open end of the Silo is rolled over a solid flexible silicone ring which is compressed to allow insertion into the abdominal cavity. An adhesive dressing of suitable internal diameter to match the Silo is provided to secure the skin tabs to the skin. The distal end of the bag is reinforced with nylon mesh and has an eye cut out for suspension with the elastic silicone tubing provided. A short length of the tubing (30cm approx.) is provided and can be used to form a slip knot around the Silo.



SBIFU0111639

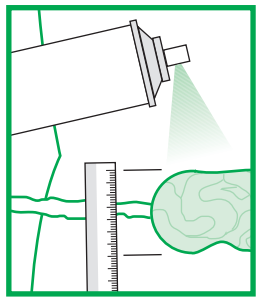
Patient Preparation

Ensure the patient is thermally and haemodynamically stable before starting Preparation should include low flow oxygen, a patent IV line, a nasogastric tube,prophylactic antibiotics and pain control as indicated.

Insertion of Silo

The Silo should be tested aseptically for patency before use. A spare device should be available at the time of operation. Usage techniques may vary in line with surgical practice but the Silos are normally placed as follows:

The defect is measured and a Silo of suitable size selected (Fig 1). All sizes are quoted as internal diameter of Silo. If the bowel is larger than the defect then a fascial incision can be made and a larger Silo used. This reduces the risk of ischemia.



SB03	**30mm diameter Silo**
SB35	**35mm diameter Silo**
SB04	**40mm diameter Silo**
SB45	**45mm diameter Silo**
SB05	**50mm diameter Silo**
SB06	**60mm diameter Silo**

Fig 1 - Select Size

The external portion of the bowel is carefully placed into a Silo of sufficient diameter and size to accommodate the bowel (Fig 2). If insertion is difficult then Langenbeck retractors can be used. The open end is then inserted into the peritoneum. The ring is compressed to allow the Silo to be inserted into the fascial ring (Fig 3).

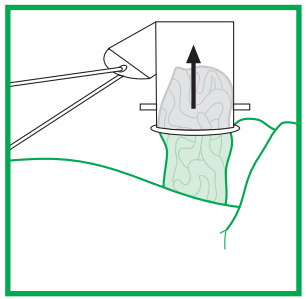


Fig 2 - Place within Silo

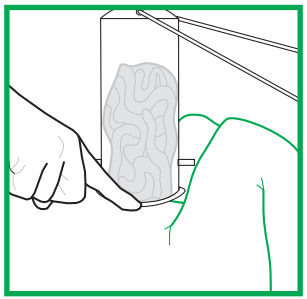


Fig 3 - Insert into Peritoneum

Prepare the skin with alcoholic solution and adhesive agent, eg Cavilon Spray. The Skin tabs are secured to the skin with silicone dressing provided (Fig 4). Care should be taken to secure this dressing as it also acts as a seal for any fluid discharge from the peritoneum. Care should also be taken to place the umbilical cord through the central hole of the dressing as in the diagram below (Fig 5). The Silo is then placed under traction with the elastic tube provided and adjusted for the most comfortable position (Fig 6).

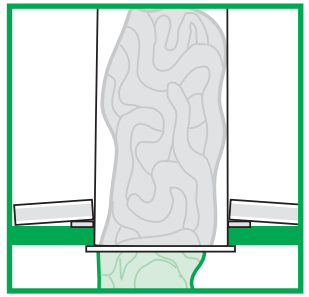


Fig 4 – Secure Skin Tabs

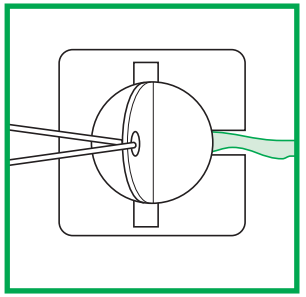


Fig 5 – Umbilical Cord Position

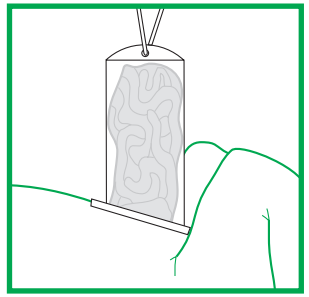


Fig 6 – Placed under Traction

Silo Reduction and Care

The bowel can then be inserted into the peritoneum twice daily in a staged manner over 3-5 days until the abdomen can accommodate the entire bowel (Fig 7). Fluid loss should be minimal and virtually eliminates the need for colloid replacement. If the Silo is being used as a temporary protection before theatre closure then the bowel is inserted in the same way. In theatre the Silo can be removed, before the procedure, by compressing the silicone ring for removal in the normal way (Fig 8).

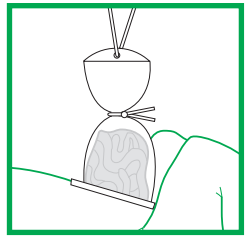


Fig 7 - Insertion into Peritoneum

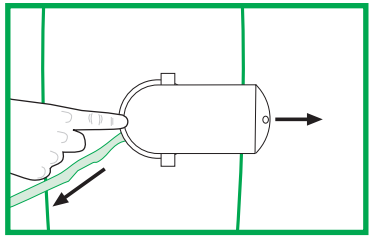


Fig 8 - Silo Removal

Removal and Closure

The skin is dried around the defect and Cavilon spray is applied. Using the cord for traction (Fig 9), pull the edges of the defect together and secure with 12mm adhesive strips. The repair is covered with a dressing eg. IV 3000 dressing, allowing the cord to protrude from the slit. The cord is allowed to dessicate. The dressing is left for 5-7 days and then removed allowing the defect to cicatrise (Fig 10), A sutured fascial closure under general anaesthesia may be necessary in some cases.

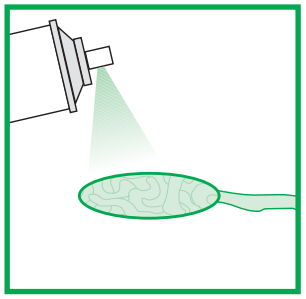


Fig 9 - Spray is Applied

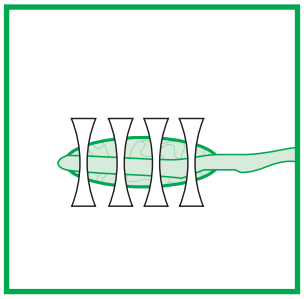
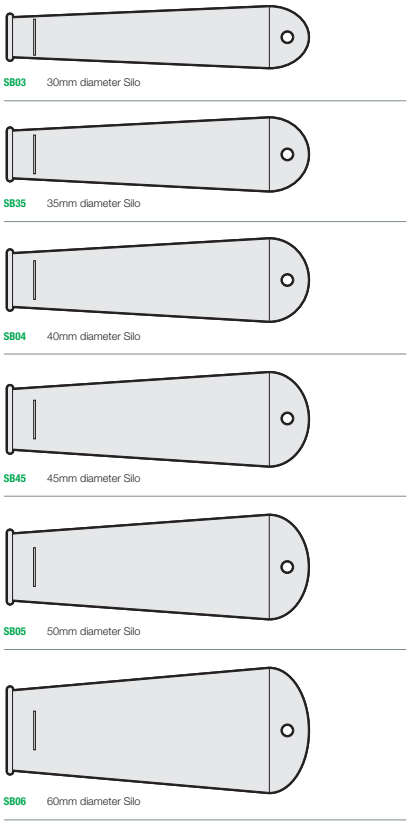


Fig 10 -Defect to Cicatrise

Precautions & Warnings

- **Please read the Instructions for Use prior to using this device.**
- **A spare device should be available at the time of operation.**
- **Infection is a common and potentially serious complication associated with this device and is most frequently caused by skin contaminants. Prophylactic antibiotics is recommended.**
- **Keep the umbilical cord moist by wrapping it in Bactigras (or similar) and cling film.**
- **Do not use if the packaging is damaged and/or sterility compromised.**
- **The device should be removed if damaged in any way.**
- **This device is supplied sterile and should be used for one patient only.**
- **This device should be used for a maximum period of 14 days.**
- **No attempt should be made to re-sterilise the device.**

Silos



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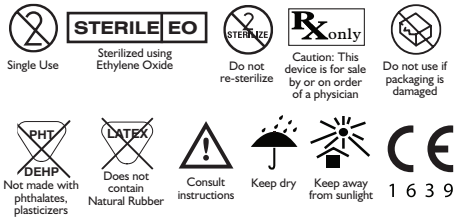

CAUTION: FEDERAL LAW (USA) restricts this device to sale by or on the order of a physician. Follow Physicians instructions using this device.

Retain the purpose built shipping box for product shipment

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EC REP **HMC Premedical S.p.A.**
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SBIFU0111639

medicina
part of HMC Group

Silo

Instructions For Use

Description: SILO IFU			
Code: SBIFU0111639		Size: W 99 mm x H 210mm	
Colours: Black and Pantone 355C		Date created: 12th April 2021	
Reason for artwork commission/revision: Change of unit number in address			
Task	Name	Signature	Date
Proofed by	Joanne Schmidt		13/04/2021
Reviewed by	Gary McMahon		13/04/2021
Approved by	Caterina Buono		13/04/2021
APPROVALSBOX001			