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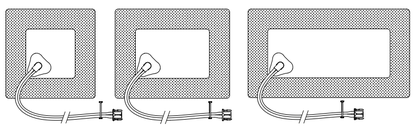
Invia® Integrated Dressing

Negative Pressure Wound Therapy



EN **Instructions for use**

ES **Instrucctiones de uso**

ENGLISH (EN)

CAUTION: Federal U.S. law restricts this device to sale by or on the order of a physician.

Only for use with Invia Negative Pressure Wound Therapy Systems

Device Description

The Invia Integrated Dressing is a sterile NPWT dressing, consisting of a pad area designed to evenly distribute the negative pressure and to draw off the exudate. A perforated silicone adhesive wound contact layer provides a gentle but secure adhesion to the skin and a double lumen tubing with Quick-connector connects the dressing to the Invia NPWT pumps.

The Invia Integrated Dressing is available in three sizes:

Description	Invia Integrated Dressing		
REF	101035697	101035698	101035699
Pad area size	10 cm x 10 cm	10 cm x 15 cm	10 cm x 25 cm
Dressing size	18 cm x 18 cm	18 cm x 23 cm	18 cm x 33 cm

Invia Black Foam NPWT is an accessory of the Invia Integrated Dressing. It is a sterile foam pad to be used when a wound filler is required.

The Invia Black Foam NPWT is available in one size:

Description	Invia Black Foam NPWT
REF	101035701
Foam pad size	10 cm x 8 cm x 3 cm

Intended use and therapy safety information

The Invia Integrated Dressing is intended for use in conjunction with the Invia Negative Pressure Wound Therapy (NPWT) Systems. The Invia NPWT Systems are intended for use in acute, extended and home care settings. Users are directed to the respective Invia NPWT System labeling for additional safety information and instruction for use. To help to ensure safe and effective use, the Invia Integrated Dressing is to be used only with the approved therapy units. The Invia Integrated Dressing is packaged sterile and for single use only.

Important: Failure to consult a physician and carefully read and follow all therapy unit and dressing instructions for use and safety information prior to each use may lead to inadequate performance of the product and/or potential for serious or fatal injury. Do not adjust therapy unit settings or use unit without directions from or supervision by the prescribing physician.

Indications for use

The Invia Integrated Dressing in conjunction with the Invia NPWT Systems is indicated for patients who would benefit from a suction device (NPWT) as when used on open wounds it creates an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.

When used on closed surgical incisions, the Invia Integrated Dressing is also intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of Negative Pressure Wound Therapy.

The Invia Integrated Dressing is appropriate for use for the following indications:
- Acute or sub-acute wounds
- Chronic wounds
- Dehisced wounds
- Pressure ulcers
- Diabetic/neuropathic ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Partial thickness burns
- Flaps and grafts
- Closed surgical incisions

Contraindications

- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in wound (with exception of palliative care to enhance quality of life)
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site of blood vessels or bypasses
- Exposed organs

Warnings, Cautions and safety instructions

⚠ WARNINGS Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTIONS Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

☛ Safety related tip Indicating useful information about the safe use of the device.

⚠ **WARNINGS**
- This device is to be used by healthcare professionals only.
- Do not use if sterile package is damaged or opened prior to use.
- When using the Invia Integrated Dressing in combination with a wound filler, pay attention to its additional specific warnings listed under section "Use of wound filler" and "Wound filler changes".
- Inspect the wound thoroughly to ensure that all pieces of dressing components (including foam or gauze) have been removed.

Bleeding
With or without using therapy, certain patients are at high risk of bleeding complications. The following types of patients are at an increased risk of bleeding, which, if uncontrolled, could be potentially fatal:
- Patients who have weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to:
  – Suturing of the blood vessel (native anastomosis or grafts)/organ
  – Infection
  – Trauma
  – Radiation
- Patients without adequate wound hemostasis
- Patients who have been administered anticoagulants or platelet aggregation inhibitors
- Patients who do not have adequate tissue coverage over vascular structures

Hemostasis, anticoagulants and platelet aggregation inhibitors
Patients without adequate wound hemostasis have an increased risk of bleeding, which, if uncontrolled, could be potentially fatal. These patients should be treated and monitored in a care setting deemed appropriate by the treating physician.

Caution should be used in treating patients on doses of anticoagulants or platelet aggregation inhibitors thought to increase their risk for bleeding (relative to the type and complexity of the wound). Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.

Hemostatic agents applied at the wound site
Non-sutured hemostatic agents (for example, bone wax, absorbable gelatin sponge, or spray wound sealant) may, if disrupted, increase the risk of bleeding, which, if uncontrolled, could be potentially fatal. Protect against dislodging such agents. Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.

Sharp edges
Bone fragments or sharp edges could puncture protective barriers, vessels, or organs causing injury. Any injury could cause bleeding, which, if uncontrolled, could be potentially fatal. Beware of possible shifting in the relative position of tissues, vessels or organs within the wound that might increase the possibility of contact with sharp edges. Sharp edges or bone fragments must be eliminated from the wound area or covered to prevent them from puncturing blood vessels or organs before the application of therapy. Where possible, completely smooth and cover any residual edges to decrease the risk of serious or fatal injury, should shifting of structures occur. Use caution when removing dressing components from the wound so that wound tissue is not damaged by unprotected sharp edges.

If therapy is prescribed for patients who have an increased risk of bleeding complications, they should be treated and monitored in a care setting deemed appropriate by the treating physician.

If active bleeding develops suddenly or in large amounts during therapy, or if frank (bright red) blood is seen in the tubing or in the canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding and seek immediate medical assistance.
The therapy units and dressings should not be used to prevent, minimize or stop vascular bleeding. Do not resume the use of the therapy system until adequate hemostasis has been achieved and the patient is not at risk of continued bleeding.

Protect vessels and organs
All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of therapy. Always ensure that the dressing does not come in direct contact with vessels or organs. Use of a thick layer of natural tissue should provide the most effective protection. If a thick layer of natural tissue is not available or is not surgically possible, multiple layers of fine-meshed, non-adherent material or bioengineered tissue may be considered as an alternative, if deemed by the treating physician to provide a complete protective barrier. If using non-adherent materials, ensure that they are secured in a manner as to maintain their protective position throughout therapy. Caution should be taken when treating large wounds that may contain hidden vessels, which may not be readily apparent. The patient should be closely monitored for bleeding in a care setting deemed appropriate by the treating physician.

Infected blood vessels
Infection may erode blood vessels and weaken the vascular wall which may increase susceptibility to vessel damage through abrasion or manipulation. **Infected blood vessels are at risk of complications, including bleeding, which, if uncontrolled, could be potentially fatal. Extreme caution should be used when therapy is applied in close proximity to infected or potentially infected blood vessels.** (Refer to protect vessels and organs section above.)

Infected wounds
Infected wounds should be monitored closely and may require more frequent dressing changes than non-infected wounds, dependent upon factors such as wound conditions and treatment goals. Refer to dressing changes instructions for details regarding dressing change frequency. As with any wound treatment, clinicians and patients/caregivers should frequently monitor the patient's wound, periwound tissue and exudate for signs of infection, worsening infection, or other complications. Some signs of infection are fever, tenderness, redness, swelling, itching, rash, increased warmth at the wound or periwound area, purulent discharge, or strong odor. Infection can be serious, and can lead to complications such as pain, discomfort, fever, gangrene, toxic shock, septic shock and/or fatal injury. Some signs or complications of systemic infection are nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucus membranes, disorientation, high fever (>102 °F, 38.8 °C), refractory and/or orthostatic hypotension, or erythroderma (a sunburn-like rash).
If there are any signs of the onset of systemic infection or advancing infection at the wound site, contact a physician immediately to determine if therapy should be discontinued.

Osteomyelitis
The therapy system should NOT be initiated on a wound with untreated osteomyelitis. Consideration should be given to thorough debridement of all necratic, nonviable tissue, including infected bone (if necessary), and appropriate antibiotic therapy.

Protect tendons, ligaments and nerves
Tendons, ligaments and nerves should be protected to avoid direct contact with dressing. These structures may be covered with natural tissue, meshed non-adherent material, or bioengineered tissue to help minimize risk of desiccation or injury.

Defibrillation
Remove the dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and/or patient resuscitation.

Magnetic Resonance Imaging (MRI)
- Therapy Unit: Invia NPWT systems are not for use in the Magnetic Resonance (MR) Environment, so do not take an Invia NPWT device into this environment.
- Dressings: After disconnecting from the Invia NPWT system, dressings can typically remain on the patient with no risk in a MR environment (all components are electrically nonconductive and nonmagnetic items).

Hyperbaric Oxygen Therapy (HBOT)
- Therapy Unit: Do not bring Invia NPWT systems into HBOT Chamber
- Dressings: After disconnecting the Invia NPWT system from the dressing, either (i) replace the dressing with another HBOT compatible material during the hyperbaric treatment or (ii) cover the unclamped end of the tubing with moist cotton gauze and completely cover the dressing (including tubing) with a moist towel throughout the treatment in the chamber. **For Hyperbaric Oxygen Therapy, the tubing must not be clamped.**

Course of therapy
Invia Negative Pressure Wound Therapy Instructions advise 24 hours therapy without interruption. If therapy is discontinued for more than 2 hours, the dressing should be replaced, and therapy restarted by a healthcare professional. If the therapy needs to be interrupted, the tubing should be clamped, and the ends of the tubing protected.

⚠ **CAUTIONS**
- This device should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which the dressing is being used.
- Do not use accessories other than those specified or sold by the manufacturer.
- Do not cut through the Invia Integrated Dressing as this will compromise the integrity of the dressing.
- Do not use with oxidizing solutions such as hypochlorite or hydrogen peroxide, as these can break down the absorbent polyurethane component of the dressing.
- Ensure the wound fits comfortably within the pad area of the dressing to ensure an effective therapy among the entire surface of the wound. Choose a different appropriate dressing if pad area of the Invia Integrated Dressing does not fit comfortably on the wound.
- Wounds greater than 0.5 cm in depth are likely to require a wound filler to ensure adequate treatment of all the wound surfaces.
- When using the Invia Integrated Dressing in combination with a wound filler, pay attention to its additional specific cautions listed under section "Use of wound filler" and "Wound filler changes".

☛ The following statements describe medical conditions that may require special care for the safe and effective use of the dressing.
- Patients untreated for malnutrition.
- Noncompliant or combative patients.
- Patients suffering from wounds in close proximity to blood vessels or delicate fascia.
- Wounds that involve an enteric fistula.
- Use near vagus nerve (bradycardia).
- Circumferential dressing application.
- The device has not been studied on pediatric patients.
- Patient size and weight should be considered when prescribing this device.

☛ For maximum benefit on closed surgical incision, the Invia negative pressure therapy should be applied immediately post-surgery to clean surgically closed wounds. It is to be continuously applied for a minimum of two days up to a maximum of seven days with dressing changes if required. All dressing changes should be applied under direct medical supervision. The Invia therapy system will not be effective in addressing complications associated with the following:
- Ischemia to the incision or the incision area
- Untreated or inadequately treated infection
- Inadequate hemostasis of the incision
- Cellulitis of the incision area

☛ Do not use the product if any information on the label is missing or obscured.

☛ The total use of the Invia Integrated Dressing should not exceed 30 days.

Wound preparation

⚠ **WARNING**
- Inspect the wound thoroughly to ensure that all pieces of dressing components (including foam or gauze) have been removed.

⚠ **CAUTION**
- Do not use with oxidizing solutions such as hypochlorite or hydrogen peroxide, as these can break down the absorbent polyurethane component of the dressing.

☛ While the concomitant use of surgical drains is allowable with the Invia therapy system, the system must not be used as an outlet or reservoir to the drain. Surgical drains must be routed under the skin beyond the boundary of the dressing and function independently of the Invia NPWT System.

Remove and dispose of previous dressing per institution protocol. Please refer to Dressing changes section for more details.

Thoroughly clean and debride the wound as instructed by a physician and allow the skin to dry.

Assess and document wound dimensions.

Dressing application

⚠ **WARNINGS**
- To be performed by healthcare professional only.
- Do not use if sterile package is damaged or opened prior to use.
- All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of therapy. Always ensure that the dressing does not come in direct contact with vessels or organs.

⚠ **CAUTIONS**
- Do not cut through the Invia Integrated Dressing as this will compromise the integrity of the dressing.
- Ensure the wound fits comfortably within the pad area of the dressing to ensure an effective therapy among the entire surface of the wound. Choose a different appropriate dressing if pad area of the Invia Integrated Dressing does not fit comfortably on the wound.
- Wounds greater than 0.5 cm in depth are likely to require a wound filler to ensure adequate treatment of all the wound surfaces. When using a wound filler follow instructions under section "Use of wound filler" prior step 1 of the dressing application.

When applying the Invia Integrated Dressing, use clean/aseptic or sterile techniques per institution protocol.

Step 1 – Peel first release layer and place centrally over wound
Peel off first release layer and place the dressing with the adhesive side down centrally over the wound. Pay attention to tubing positioning (not kinked) to allow for optimal flow. Avoid placement of tubing over bony prominences.

Step 2 – Remove second release layer
Remove other release layer and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.

Step 3 – Connect the dressing tubing to the pump tubing
Make sure both parts of the Quick-connector are aligned correctly as shown in the picture below.

Push the Quick connector together until you hear a click.

Ensure that tubing is installed completely and without any kinks to avoid leaks or blockages in the suction circuit.

Step 4 – Turn on the pump
Turn on the pump and select the prescribed therapy setting. Do not use intermittent mode therapy setting with Invia Integrated Dressing. Ensure dressing receives negative pressure and check that seal is secure around the dressing.

Wound assessment

⚠ **WARNINGS**
Patient monitoring: The patient should be monitored regularly according to the physician's instructions and local facility guidelines to check for patient comfort, therapy compliance and signs of infection. If there are any signs of systemic infection or advancing infection at the wound site, contact the treating physician immediately. The most common signs of infection include redness, tenderness, fever, swelling, itching, increased warmth in the wound area, strong odor or purulent discharge. Additional symptoms include nausea, vomiting, diarrhea, dizziness, fainting, sore throat with swelling of the mucous membranes, disorientation, high fever (>102° F, 38.8°C), refractory and/or orthostatic hypotension, or erythroderma (a sunburn-like rash). More serious complications of infection include pain, discomfort, fever, gangrene, toxic or septic shock.

Dressing changes

The Invia Integrated Dressing can be left in place for up to 7 days. In the event of heavy drainage, drainage with sediment or infected wounds, more frequent dressing changes may be needed.

☛ When the Invia Integrated Dressing is used in combination with a wound filler, the dressing with the wound filler should be changed every 48–72 hours.

☛ As with all adhesive products apply and remove the dressing carefully from sensitive or fragile skin to avoid skin tripping, especially after frequent dressing changes.

☛ The total use of the Invia Integrated Dressing should not exceed 30 days.

Dressing Removal
1. Turn the pump off.
2. Close the clamp on the dressing tubing.
3. Close the clamp on the pump tubing.
4. Disconnect the pump tubing from the dressing tubing by pressing on the sides of the Quick-connector.
5. Remove gently the dressing from the skin.
6. If wound filler was used note warnings/cautions under section "Wound filler changes" and remove the foam/gauze from the wound.
7. Dispose of the dressing in accordance with local guidelines.
8. Prepare the wound for the next dressing as described under "Wound preparation".

Use of wound filler

The Invia Integrated Dressing is compatible with all Invia wound fillers (foam or gauze).

⚠ **WARNINGS**
- Always count and document the total number of pieces of foam/gauze used in the wound to ensure the same number of foam/gauze pieces was removed as placed.
- Do not place foam/gauze into blind or unexplored tunnels.

⚠ **CAUTIONS**
- Avoid overlapping of foam/gauze onto intact skin.
- Do not cut foam/gauze directly over the wound bed to avoid foam/gauze fragments from falling into the wound. Away from the wound site, rub the edges of the foam to remove any loose fragements or loose particles that may fall into or be left in the wound upon dressing removal.
- Foam/gauze should be cut to fit loosely into the wound bed. Do not tightly pack or force foam/gauze into any areas of the wound as this may damage tissue, alter the delivery of negative pressure, or hinder exudate and foam/gauze removal.
- If a tunnel exists, cut the foam/gauze longer than the tunnel to ensure that contact is made with the foam/gauze in the primary wound bed/cavity. Invia White Foam may be appropriate for use with explored tunnels. If using Invia black foam in a tunnel, ensure it is wrapped in a non-adherent layer to prevent any breakage at removal.
- When using Invia Integrated Dressing in combination with an Invia wound filler, apply negative pressure settings of –80 mmHg or higher to allow for optimal fluid removal.

☛ When used with Invia foam/gauze, the use of negative pressure presents a risk of tissue ingrowth into the foam/gauze. Tissue ingrowth may be reduced by reducing therapy pressure, using a wound contact layer or by increasing the frequency of dressing changes.

When applying Invia wound fillers, use clean/aseptic or sterile techniques per institution protocol.

1. Cut foam/gauze to fit size and shape of the wound.
2. Rub edges of the foam to remove any loose fragments after cutting. When using gauze, saturate gauze with saline.
3. Place foam/gauze into the wound cavity.
4. Avoid overlapping of foam/gauze onto intact skin. If required, a non-adherent layer may be applied to the wound prior to placing the foam/gauze into the wound bed.
5. Record number of foam/gauze pieces used onto the dressing and patients notes.

Wound filler changes

⚠ **WARNING**
Ensure the same number of foam/gauze pieces that were placed in the wound have been removed. Foam/gauze left in the wound for greater than the recommended time period may foster ingrowth of tissue into the foam/gauze, create difficulty in removing foam/gauze from the wound, or lead to infection or other adverse events. Regardless of treatment modality, disruption of new granulation tissue during any dressing change may result in bleeding at the wound site. Minor bleeding may be observed and considered expected. However, patients with increased risk of bleeding, as described in the Warnings section under Bleeding, have a potential for more serious bleeding from the wound site.

⚠ **CAUTION**
If foam/gauze adheres to wound, apply saline into the dressing and wait for 15–30 minutes before gently removing the foam/gauze.

☛ If the patient experiences discomfort during the dressing change, consider premedication, the use of non-adherent wound contact layer before foam/gauze placement, or managing the discomfort as prescribed by the treating physician.

Signs and symbols

℞ only This symbol indicates a prescription device. CAUTION: Federal US law restricts this device to sale by or on the order of a physician. (for US only).[1]	Indicates the need for the user to consult the instructions for use.[2]	This symbol indicates the medical device manufacturer.[3]
Indicates the date when the medical device was manufactured.[4]	MD Indicates the item is a medical device.[5]	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.[6]
Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.[7]	REF Indicates the manufacturer's catalogue number so that the medical device can be identified.[8]	LOT Indicates the manufacturer's batch code so that the batch or lot can be identified.[9]
To identify the country of manufacture of products.[10]	Indicates a single sterile barrier system.[11]	Indicates a medical device that needs to be protected from moisture.[12]
Indicates to peel here.	This symbol indicates safety related tip.	Indicates a medical device that is intended for one single use only.[13]
STERILE EO Indicates a medical device that has been sterilized using ethylene oxide.[14]	Indicates the date after which the medical device is not to be used.[15]	10 Indicates the quantity of individual devices in pack.
pcs Indicates number of items.	Indicates a medical device that can be broken or damaged if not handled carefully.[16]	Indicates a single sterile barrier system with protective packaging outside.[17]
Indicates a medical device that needs protection from light sources.[18]		

Transport and store in dry conditions at room temperature.

References:
1 FDA Guidance Alternative to Certain Prescription Device Labeling Requirements
2 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.4.4, Consult Instructions for Use
3 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.1 Manufacturer
4 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.3 Manufacturing Date/ISO 7000-2497, Graphical symbols for use on equipment, Date of manufacture
5 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.7.7, Medical Device
6 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.4.4, Caution
7 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.2.8, Do not use if package is damaged and consult instructions for use
8 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.6 Article number/ISO 7000-2493, Graphical symbols for use on equipment, Catalogue number
9 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.5 Batch code/ISO 7000-2607, Graphical symbols for use on equipment, Batch code
10 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.11 Country of manufacture/IEC 60417-6049, Graphical symbols for use on equipment, Country of manufacture
11 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.2.11, Single sterile barrier system/ISO 7000-3707, Graphical symbols for use on equipment, Single sterile barrier system
12 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.4, Keep away from rain/ISO 7000-0626, Graphical symbols for use on equipment, Keep away from rain
13 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.4.2, Do not re-use/ISO 7000-1051, Graphical symbols for use on equipment, Do not re-use
14 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.2.3 Sterilized using ethylene oxide/ISO 7000-2501, Graphical symbols for use on equipment, Sterilized using ethylene oxide
15 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.4 Use by date/ISO 7000-2607, Graphical symbols for use on equipment, Use by date
16 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.1, Fragile, handle with care/ISO 7000-0621, Graphical symbols for use on equipment, Fragile, handle with care
17 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.2.14, Single sterile barrier system with protective packaging outside/ISO 7000-3709, Graphical symbols for use on equipment, Single sterile barrier system with protective packaging outside
18 ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.2 Keep away from sunlight/ISO 7000-0624, Graphical symbols for use on equipment, Keep away from sunlight

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