Surecan[®] Safety II

Power-injectable safety non-coring needles for Access Ports



Access Ports Systems





Surecan® Safety II needles for Access Ports

- Surecan[®] Safety II is a non-coring safety needle designed by nurses for nurses. "Health and safety of workers is paramount and is closely linked to the health of patients."*
- The small size and unique design of Surecan[®] Safety II ensures comfort for both clinicians and patients, either in hospital or for home care treatment.
- Surecan[®] Safety II is indicated for up to seven days^{**} for infusion of chemotherapy, parenteral nutrition (TPN), antibiotic therapy, transfusion and blood sampling.
- The power injectable Surecan[®] Safety II may also be used for injection of contrast media when CT scans are performed.
- Extensive choice of references
 - 19G to 22G clinical and patients needs are answered
 - 15 mm to 38 mm different lengths adapted to different patient's anatomy

Very low profile, ergonomic wings

- easy to insert and remove
- no change to existing techniquesdesigned to provide secure handling
- during puncture and removal
- intuitive deployment
- patient-friendly, permits small and comfortable dressing
- needle gauge indicated on wings



Base

- transparent base for easier visualisation of the insertion point and detection of a suspected infection
- holes to aid skin aeration to reduce risk of maceration which reduces infection risk



Needles

- non-coring bevel maximises septum life
- non-siliconised cannula to improve needle retention in septum and avoid spontaneous movement of the needle out of the port



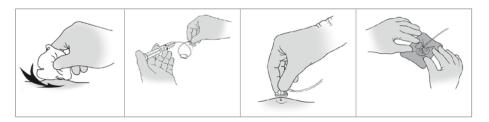
High density closed-cell pad

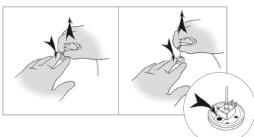
- reduces risk of infection as fluids are not absorbed into the pad
- increases patient's comfort when in contact with the skin
- closed cell design avoids bacterial exchange and compression
- low profile (1.5 mm) reduces risk of needle movement

Extension Tubing

- DEHP-free transparent and anti-kink tubing
- power injectable

* European Council Directive 2010/32/EU of 10 May 2010 ** Technical Bulletin on request





Surecan[®] Safety II needles are

- MR Conditional can be used during MRI scanning**
- DEHP/latex free suitable for many medications
- Power injectable









HIGH SECURITY at all times ...

Needle and wings clip to base

- which reduces the risk of premature separation of the needle from the base and accidental deployment
- when unclipped pulsed, rotative flushing can easily be achieved



Green point confirms correct deployment of the safety mechanism

for easy confirmation of deployment



Clamp to interrupt infusion at any time • easy handling

- colour coded to identify the gauge of the needle
- containing maximum psi information for fast and easy identification for High Pressure injection (HP)



Ultrasite[®] needle free connector with positive pressure valve (for Y-site version)

- offers additional security even during the use of the needle
- reduced risk of needle stick
- reduces the risk of blood reflux during syringe removal
- reduced risk of blood contact
- maximum pressure indicated on valve



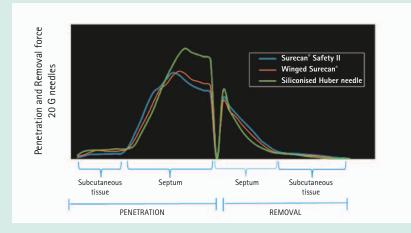
Unique crimping on the needle

- ensures non-reversible deployment
- aids needle retention in the septum during power injection



Note:

Easy to dispose in a medical sharps collector (eg. B. Braun Medibox 0.7 L)



- The force to insert the needle is similar to that of siliconised needle
- The retaining force of the needle ensures that
 - the needle does not spontaneously exit the port under the dressing
 - the risk of accidental sub-cutaneous extravasation of drugs is reduced
- the medication flows correctly



The special bevel

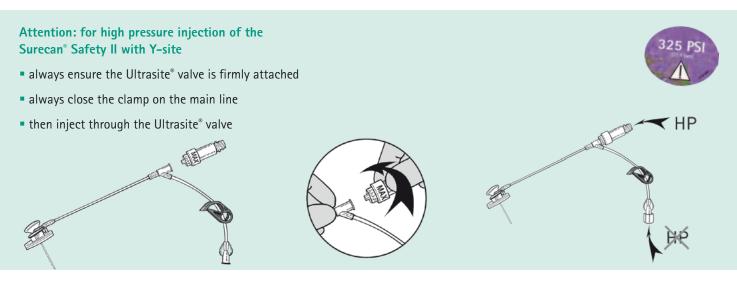
- reduces the coring of the septum
- reduces the risks associated with septum coring such as port leakage or blockage
- reduces the risks of small particles of septum entering the patient
- maximises port life

| Reference | Dead volume (mL) max |
|--|----------------------|
| Surecan [®] Safety II 19G | 0.30 |
| Surecan [®] Safety II 20G | 0.25 |
| Surecan [®] Safety II 22G | 0.20 |
| Surecan [®] Safety II with Ultrasite [®] Y 19G | 0.65 |
| Surecan [®] Safety II with Ultrasite [®] Y 20G | 0.60 |
| Surecan $^{\circ}$ Safety II with Ultrasite $^{\circ}$ Y 22G | 0.50 |

| | | | | | Tubing length | | | | |
|--|----------------|----------------|----------|----------|---------------|----------|----------|---------------------|------------------------|
| Available in boxes of 20 units | Needle Size | Colour Code | 15 mm | 20 mm | 25 mm | 32 mm | 38 mm | Needle to Connector | |
| Surecan [®] Safety II | 19G | | 04447000 | 04447001 | 04447002 | 04447003 | 04447004 | 190 +/-10 mm | |
| | 20G | | 04447005 | 04447006 | 04447007 | 04447008 | 04447009 | | |
| | 22G | | 04447010 | 04447011 | 04447012 | 04447013 | - | | |
| Available in boxes of 20 units | Needle Size | Colour Code | 15 mm | 20 mm | 25 mm | 32 mm | 38 mm | Needle to Y-Site | Y-Site to connector |
| Surecan [®] Safety II with Ultrasite [®] Y | 19G | | 04447028 | 04447029 | 04447030 | 04447031 | 04447032 | | |
| | 20G | | 04447033 | 04447034 | 04447035 | 04447036 | - | 90 +/-10 mm | 82 +/-10 mm |
| | 22G | | 04447038 | 04447039 | 04447040 | - | - | | |

Guidelines for using Surecan[®] Safety II needles for CECT

All Surecan® Safety II needle configurations are power injectable**



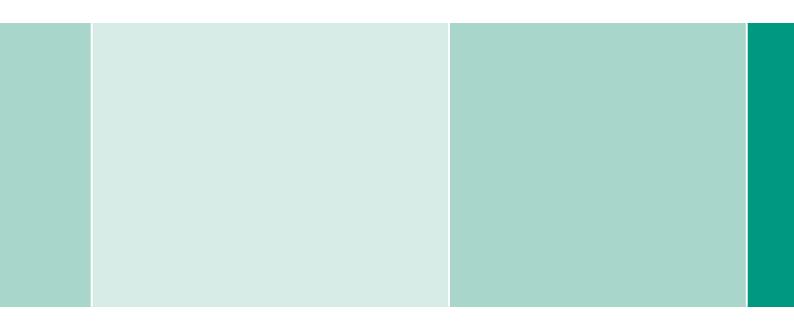
Surecan[®] Safety II with Ultrasite[®] Y

Surecan[®] Safety II needles may be used for Contrast Enhanced Computerised Tomography (CECT) using power injection

Warning for high flow rate/power injection:

- Always verify that the access port implanted is power injectable.
- Always verify that the port and catheter are functional by aspirating 2mL of blood into a syringe and injecting 5mL of sodium chloride (NaCl) 0.9% into the port/catheter before attempting to start an infusion of medication.
- Do not exceed the recommended pressure (325psi 22.4 bars) and access port maximum flow rate recommended by the manufacturer as device failure may occur.
- Do not exceed the maximum pressure indicated on the needle (325psi).
- Contrast media should be warmed to 37°C (98.6°F) before use.
 Failure to do so will result in up to 50% lower flow rates and/or device failure.

- Depending on the technical characteristics of the injector system, the target flow rate might not be attained.
- Ensure that the needle is correctly placed in the port, securely taped to the skin and covered with an adhesive dressing before starting high pressure injection.
- Vigorously flush the Surecan[®] Safety II needle using a 10 ml or larger syringe and sterile sodium chloride (NaCl) 0.9% prior to and immediately following the completion of power injection studies.
- The Surecan® Safety II indication for power injection of contrast media implies the ability of the system to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.



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