



## Surecan™ Safety II Port Access Needle

Does Surecan Safety II contain DEHP or latex?

Surecan Safety II needles are not manufactured with DEHP or natural rubber latex.

Can I use the Surecan Safety II needle with a power injector?

Yes, all the Surecan Safety II needles can be used for power injection.

**Note:** The Surecan Safety II needle with CARESITE® requires injection through the CARESITE valve, and not through the distal end of the tubing.

Are the Surecan Safety II needles MRI conditional?

Yes, Surecan Safety II needles are MRI conditional (See product IFU).

Non-clinical testing has demonstrated the devices are MRI conditional. They can be safely scanned under the following conditions:

- Static magnetic field of 3 Tesla and 1.5 Tesla
- Maximum spatial gradient magnetic field of 710 Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg. Under these scan conditions, the Surecan Safety II needle is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 25 mm from the device when imaged with a gradient echo pulse sequence and a 3T MRI system.

The IFU and labels state the Surecan Safety II needles can be used for power injection up to 325 psi. Why does the clamp on the Y-Site configurations show 45 psi?

Power injection up to 325 PSI should always be applied through the CARESITE valve at the Y-Site. Forty five (45) PSI is the maximum pressure allowed through the injection port at the distal end of the infusion set.

How long can a Surecan Safety II needle be left in the port?

Surecan Safety II needles may be used for up to seven days, in the absence of infection, redness, swelling, or pain, and in accordance with institutional protocol.

How can I prevent the base plate from sliding down the needle during port access?

The base plate is secured by a small retention plate under the wings. Grasp the wings and fold vertically to prevent unintentional unclipping of the base plate. Grasp the wings to prepare for insertion. Keep fingers off of the base plate. Remove the needle guard with the other hand.

Do you have any suggestions for dressing the Surecan Safety II needle?

Dress the device per institutional protocol. B. Braun suggests placing two adhesive strips over the wings and one over the extension set. Apply a clear dressing over the entire Port Access needle in a manner to prevent tenting.

What is the gravity flow rate for the Surecan Safety II needle?

TABLE 1.1

Gauge	Needle Length	NaCl mL/min¹ (average)
19G	20 mm (0.8 in)	38.9
19G	25 mm (1.0 in)	38.6
19G	38 mm (1.5 in)	35.5
20G	20 mm (0.8 in)	20.2
20G	25 mm (1.0 in)	21.5
20G	38 mm (1.5 in)	21.3
22G	15 mm (0.6 in)	8.9
22G	25 mm (1.0 in)	7.7
22G	32 mm (1.3 in)	7.8

What does "useable length" of the needle mean?

The length for Surecan Safety II needles is measured from the lower level of the foam pad to the tip of the needle. The length of the needle stated on the packaging is the "usable length," meaning the length of the needle that can be inserted. See table below.

<u>It is important to remember this when converting from other needles to Surecan Safety II needles, to use Table 1.2 to determine appropriate needle lengths.</u>

TABLE 1.2

	B. Braun Surecan Safety II	Smiths Gripper Plus	Bard EZ Huber	Bard Safestep
Length on packaging <sup>2</sup>	0.8"	0.75"	0.75"	0.75"
Usable length <sup>2</sup>	0.8"	0.62"	0.62"	0.68"

Can I use the Bio-Patch dressing with the Surecan™ Safety II Needle? Yes, Bio-Patch can be used with Surecan Safety II needles. Follow the Bio-Patch manufacturer's IFU.

Are the Surecan Safety II Port Access Needles siliconized? No. Like other port access needles, there is no silicone on the needles.

Removing occlusive dressings can be difficult. Do you have any recommendations? Support the Surecan Safety II needle with one hand while removing the dressing.



How is Surecan Safety II sterilized? Surecan Safety II is sterilized by ethylene oxide (also known as EO or EtO).

What are the materials of the Surecan Safety II Needle components?

TABLE 1.3

Component Name	Raw Material		
Wing	Polyvinyl Chloride (PVC) / Trioctyl Trimellitate (TOTM)		
Needle Cannula, Bushing, Safety Plate	Stainless Steel		
PUR tube	Polyurethane (PU)		
Bottom, Base	Acrylonitrile butadiene styrene (ABS)		
Foam	Polyethylene (PE)		
Luer Connector, Y-Site	Polyvinyl chloride (PVC)		
Closing Cone	Polystyrol (PS)		
Protective tube	Polyethylene (PE)		
Pinch Clamp	Polypropylene (PP) / colorant / ink		
CARESITE	Polycarbonate / Silicone		

Refer to product labeling for complete instructions for use.

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Engineering Test Data on File (TB1302; TB812; TB919)
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