



**PART I**

**GENERAL DESCRIPTION**

## INTRODUCTION

The technical file gathers and identifies information that demonstrates compliance of our hypodermic needles with the requirements of the 93/42/CEE Regulation.

Note: Information and documents which are not included in the technical file may be available if required.

### I.1 Proprietary name

**SOFIJET**

**XL by SOFIC**

### I.2 Product description

Sterile, siliconised, two-point needles for cartridge syringes.

These needles are single-use and non-sterilisable.

XL by SOFIC: For dental use only.

#### o *Common characters*

> Silicone-coated cannula: the cannula is treated with silicone for better penetration of the needle into tissues.

> Stainless steel of the cannula in compliance with the ISO 9626 standard.

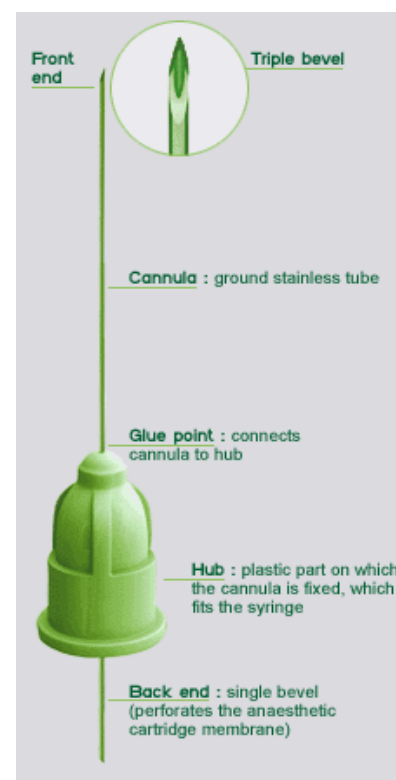
> Threaded hub: the plastic hub thread complies with the ISO 7885 standard relative to « sterile dental injection needles for single use », and fits any syringe complying with the ISO 9997 standard relative to « dental cartridge syringes ». There are 2 types of threading: inch thread (also called American or non metric) and metric thread (also called European). These 2 threads have different dimensions.

> Two bevelled points: one intended for the injection properly, the other one entering into the syringe and intended for perforating the cartridge when inserted.

> Bevel indicator: helps localize the bevel and thus aids the practitioner in the accurate placement of all injections.

> Paper seal: coloured label sealing the needle that helps identify the diameter and length of the needle, the batch number, the expiry date and the sterilisation mode

> Ethylene oxide and gamma irradiation sterilisation: needles are sterilised through gamma irradiation or under ethylene oxide, validated processes under constant control.



○ **Features and Benefits**

**SOFIJET**

> Standard inside diameter: pressure is high. The liquid flow is thin and penetrates quickly.

> Triple bevel: the front end of the cannula is ground to allow smoother penetration into tissues and reduce the possibility of tissue damage.



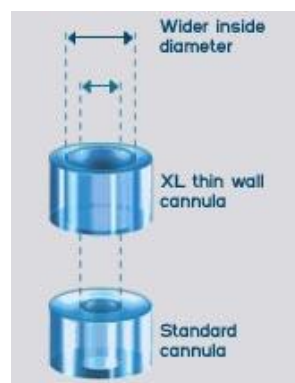
**Standard bevel**

**XL by SOFIC**

> XL needles have the same external dimensions as ordinary needles but have an internal diameter up to 38% wider for the 30G and 42% wider for the 27G. This means that less pressure is required when injecting to administer the same volume of anaesthetic, giving a more sensitive control of flow rate with the benefit of a gentler injection for the patient

> Thin wall cannula: pressure is less high. The liquid flow is wide and penetrates slowly, with better respect of tissue.

> Coloured cap according to the ISO 7885 standard: yellow for 30G and grey for 27G: helps identify the needle.



**XL bevel**

		Inner diameter	
		Regular wall	Thin wall
30G	min	0,133	0,165
	max	0,143	0,175
27G	min	0,184	0,241
	max	0,194	0,251

		Lumen (mm <sup>2</sup> )	
		Regular wall	Thin wall
30G	min	0,013892908	0,021382465
	max	0,016060607	0,024052819
27G	min	0,02659044	0,045616711
	max	0,029559245	0,04948087

Surface increase RW vs TW%		
	30G	27G
min	33%	54%
max	73%	86%
average	53%	70%

### **I.3 Indications and instructions for use**

#### ***I.3.1 Indications***

- |                    |                                 |
|--------------------|---------------------------------|
| ○ <i>SOFIJET</i> : | ○ <i>XL by SOFIC</i>            |
| Medical use:       | Dental use only:                |
| - subcutaneous     | - local injections,             |
| - intradermal      | - regional injections,          |
|                    | - intra-septal injections,      |
|                    | - intra-ligamentous injections. |
|                    | - intra-osseous                 |

#### ***I.3.2 Instructions for use***

For single use only.

Store in original packaging until ready to use.

#### **Instructions For Use:**

Break the sterility guarantee seal just before use by turning the two parts of the protective sleeve in opposite directions.

Screw the pre-threaded needle onto the pre-threaded hub of the syringe.

Remove the plastic cap just before the injection is administered. It can be used again to remove the needle from the syringe to avoid risk of needle stick injury.

Discard the used needle into a puncture-resistant container in accordance with all applicable medical waste regulations.

#### **Warnings:**

Never recap needles by hand. Use only accepted dental recapping procedures. Recapping needles by hand or recapping bent or broken needles can cause unintended needle sticks.

Do not bend, break, or otherwise stress needles as serious injuries to you and/or your patient can occur.

Do not insert needle to hub during injections, as needles can break and become lodged in patient's tissue, potentially causing serious permanent injury. Do not use short needles (<30mm) when the expected depth in soft tissue approaches the length of the needle.

Avoid extreme pressure and excessive needle movement during injection as this may cause needles to break, which may result in serious injury to you and/or your patient.

Be especially vigilant when repositioning a needle in a patient who appears to be apprehensive.

*For XL needles: avoid either too rapid of an injection and/or excessive pressure as that may lead to increased patient pain during injection*

**Cautions:**

Store in original packaging until ready to use.

Read the Instructions For Use supplied with your injection device.

If seal is broken, the needle is NOT STERILE and MUST NOT BE USED.

For single use only: This device is for use in a single patient. Any reuse exposes other patients and the user to critical risks, including infection and trauma since the needle is no longer sterile and is more likely to break."

If multiple injections are required, replace the needle for each cartridge in order to minimize the risk of needle point damage.

1 patient / 1 cartridge / 1 needle

*Because XL needles have a larger lumen (bore) than other needles, prior to injection, soft tissue should be stabilized to reduce the risk of needle deflection.*

**I.4 Classification of the medical device*****Directive 93/42/EEC - Annex IX***

Class IIa, rule 6: *"All invasive devices of a surgical nature intended for temporary use are included in class IIa."*

**GMDN code:** 12740 – Needle,dental

***Other applicable Directives:***

Not applicable.

According to Schedule 1 Rule 1 of the Canadian Medical Devices Regulations SOR/98-282 7 may 1998, these devices are rules as:

Surgically Invasive Devices Class II

**I.5 Statement indicating whether or not the device incorporates an ancillary medicinal substance**

Not applicable, the device does not contain an ancillary medicinal substance.

**I.6 Statement indicating whether or not the device incorporates a human blood derivative**

The product does not contain human blood derivatives.

**I.7 Statement indicating whether or not the device is manufacturing utilising tissues of animal origin**

No products of animal origin are used in the manufacture of this product.

**I.8 Variants**

**I.8.1 Presentation**

Box containing 100 needles.

<b>SOFIJET Needle Sizes available</b>	<b>In mm (I.S.)</b>	<b>Diameter in Gauge</b>	<b>Type of injection</b>
Extrashort	0.3 x 08 mm	30 Ga	Intraligamentary
Extrashort	0.3 x 10 mm	30 Ga	Intraligamentary
Extrashort	0.3 x 12 mm	30 Ga	Short bevel: Intraligamentary Standard bevel: intraligamentary and periapical
Short	0.3 x 16 mm	30 Ga	Standard bevel : periapical Short bevel : intraligamentary
Short	0.3 x 21 mm	30 Ga	Periapical
Short	0.3 x 23 mm	30 Ga	Periapical
Short	0.3 x 25 mm	30 Ga	Periapical
Extrashort	0.4 x 08 mm	27 Ga	Standard bevel : intraseptal Short bevel : intraligamentary
Extrashort	0.4 x 12 mm	27 Ga	Intraseptal
Short	0.4 x 16 mm	27 Ga	Periapical
Short	0.4 x 21 mm	27 Ga	Periapical
Short	0.4 x 23 mm	27 Ga	Periapical
Short	0.4 x 25 mm	27 Ga	Periapical
Long	0.4 x 35 mm	27 Ga	Nerve block
Long	0.4 x 42 mm	27 Ga	Nerve block
Long	0,40 x 38 mm	27 Ga	Tronculaire/Nerve block
Extrashort	0.5 x 08 mm	25 Ga	Intraseptal
Short	0.5 x 25 mm	25 Ga	Periapical
Long	0.5 x 35 mm	25 Ga	Nerve block
Long	0.5 x 42 mm	25 Ga	Nerve block

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Short	0.3 x 21 mm	30 Ga	Periapical
Short	0.3 x 23 mm	30 Ga	Periapical
Short	0.3 x 25 mm	30 Ga	Periapical
Extrashort	0.4 x 08 mm	27 Ga	Intraseptal
Short	0.4 x 16 mm	27 Ga	Periapical
Short	0.4 x 21 mm	27 Ga	Periapical
Short	0.4 x 25 mm	27 Ga	Periapical
Long	0.4 x 35 mm	27 Ga	Nerve block
Long	0.4 x 42 mm	27 Ga	Nerve block

### ***1.8.2 Equivalence***

Not applicable.