

## TECHNICAL SHEET

## BONE INJECTION NEEDLES BEVELED TIPS – PLASTIC

<b>Commercial name</b>	Bone injection needle beveled tip
<b>Manufacturer's reference</b>	See table below
<b>Packaging</b>	PE sachet in Tyvek pouch. To improve the safety of the sterile packaging, the cannula of the needles is protected with a PE tubing.
<b>Sterilization – Shelf life</b>	Sterilization: Ethylene Oxide Shelf life: 3 years.
<b>Product description</b>	Beveled tip with triple sharpening; graduated cannula; Luer-Lok connection; suitable for biopsy purposes
<b>Composition</b>	Cannula: steel AISI 304; stylet: steel AISI 302; handgrip: PP; Luer Lock cone and stylet knob: nickel-plated brass
<b>Quality controls</b>	<u>Raw materials</u> : visual check, tensile and torsion tests. <u>End product</u> : visual inspection, label's verification, sterilization certificate check. <u>Packaging</u> : dimensional inspection, weld joint control (peeling test), leak test (methylene blue), control of weld thickness.
<b>Configuration</b>	1 Bone Injection Needle
<b>M.D. classification</b>	Ila according to CEE 93/42
<b>Intended use</b>	Needle for acrylic bone cement injection into vertebral body.
<b>Latex content</b>	The medical device and its packaging are latex-free
<b>Biocompatibility</b>	The component of the device which comes in contact with the human body is made with stainless steel suitable for medical use (ISO 9626).
<b>Warnings and storage conditions</b>	The device is sterile unless the packaging is open or damaged. The device is single-use and intended for use on a single patient. Do not re-sterilize or re-use. Re-sterilization may cause an infection risk to the patient.
<b>Disposal</b>	All wastes should be considered surgical material and must be disposed as such at the end of surgery.
<b>Release of chemicals</b>	N/A

Ref.	Description
ASB0000	Beveled tip needle    G:09    L:15 cm
ASB0010	Beveled tip needle    G:11    L:12 cm
ASB0020	Beveled tip needle    G:13    L:12 cm
ASB0120	Beveled tip needle    G:15    L:12 cm

Release date: 18/12/2015

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Rev	Date	Description of changes
00	30/09/08	New issue
01	18/12/15	New format. Information updating