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EN

INSTRUCTIONS FOR USE

POLYMER GUIDEWIRE WITH HYDROPHILIC COATING, ENTER

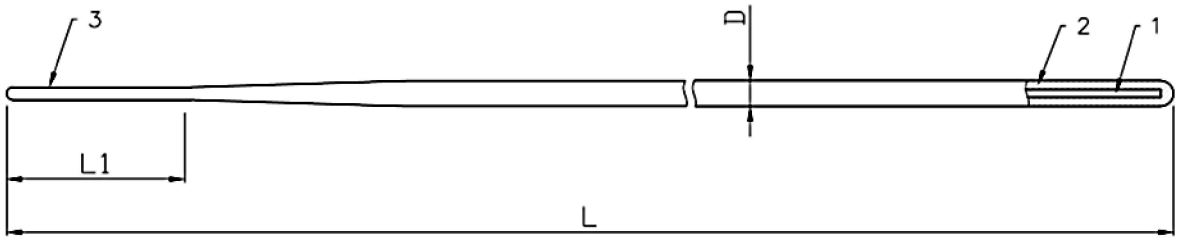
ENTER™

CE 0197

READ THESE INSTRUCTIONS BEFORE USE

1. DEVICE DESCRIPTION

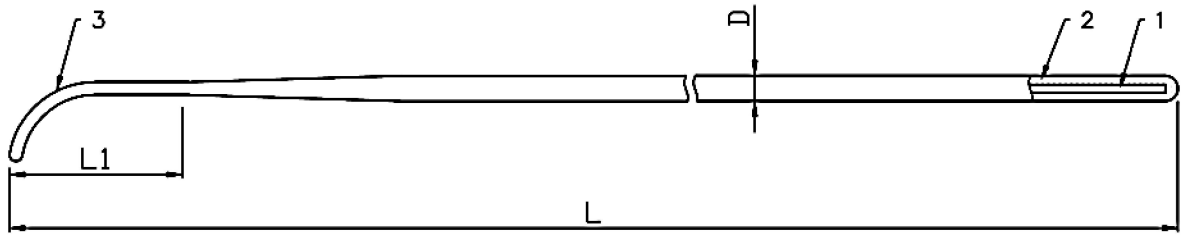
The polymer guidewire with a hydrophilic coating Enter consists of a nickel-titanium alloy (nitinol) core wire coated with radiopaque polyurethane. The distal part of the guidewire may have a straight or angled tip.



1. Nitinol core
2. Radiopaque coating
3. Distal tip

L - Guidewire legth
L1 - Distal flexible part length
D - Guidewire diameter

Fig. 1. Guidewire Enter – straight type



1. Nitinol core
2. Radiopaque coating
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L - Guidewire length
L1 - Distal flexible part length
D - Guidewire diameter

Fig. 2. Guidewire Enter – angled type

Table 1. Device parameters

Core material	Nitinol (nickel-titanium alloy)
Radiopaque coating	Polyurethane containing barium sulfate
Hydrophilic coating	Yes
Guidewire diameters	0.025''; 0.032''; 0.035''; 0.038''
Guidewire length	50 cm – 260 cm
Distal flexible part length	30 mm
Guidewire stiffness	Medium stiff for 0.025'' and 0.032"; medium stiff , stiff or floppy for 0.035'' and 0.038''
Distal tip	Straight or angled

2. PRODUCT RANGE

Table 2. Available device versions

Guidewire diameter [inch]	Guidewire stiffness	Guidewire lengths [cm]						
		50	80	120	150	180	200	260
0.025	Medium stiff	✓	✓	✓	✓	✓	✓	✓
0.032	Medium stiff	✓	✓	✓	✓	✓	✓	✓
0.035	Floppy	✓	✓	✓	✓	✓	✓	✓
	Medium stiff	✓	✓	✓	✓	✓	✓	✓
	Stiff	✓	✓	✓	✓	✓	✓	✓
0.038	Floppy	✓	✓	✓	✓	✓	✓	✓
	Medium stiff	✓	✓	✓	✓	✓	✓	✓
	Stiff	✓	✓	✓	✓	✓	✓	✓

√ - offered

3. INTENDED PURPOSE / INDICATIONS

The polymer guidewire with hydrophilic coating Enter is intended for facilitating the placement of balloon dilatation catheters and other interventional devices during endovascular procedures within peripheral arteries.

3.1. CONTRAINDICATIONS

The use of the device is usually contraindicated in the following cases:

- any cases listed as contraindications in the instructions for use of the product with which the guidewire is used;
- patients with contraindication(s) for antiplatelet / anticoagulant treatment;
- fully occluded vessel;
- allergy to device materials (polyurethane, nitinol).

3.2. POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with the use of this device include (in alphabetical order), but are not limited to:

- allergic reaction or hypersensitivity to administered anticoagulation or antiplatelet drugs, anesthesia, contrast agent or guidewire materials;
- cardiac arrhythmias;
- death;
- fever;
- guidewire entrapment / fracture;
- hypotension / hypertension;
- infection;
- lower limb artery complications:
  - abrupt closure;
  - dissection;
  - embolism (caused by air, atherosclerotic plaque, thrombotic material or device element);
  - perforation;
  - spasm;
  - thrombosis;
- nausea and vomiting;
- pain;
- palpitations, dizziness, syncope;
- renal insufficiency / failure;
- stroke / transient ischemic attack (TIA);
- vascular access complications that may require blood transfusion or vessel repair:
  - bleeding (ecchymosis, hematoma, hemorrhage, retroperitoneal hemorrhage);
  - embolism (caused by air, atherosclerotic plaque, thrombotic material or device element);
  - peripheral ischemia;
  - peripheral nerve injury;
  - pseudoaneurysm, dissection, perforation, arteriovenous fistula.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer at **reklamacje@balton.pl** and the competent authority of the country in which the user and/or patient is established.

3.3. INTENDED USER PROFILE

Intended users of this device are only physicians who have received appropriate training for endovascular procedures.

3.4. USE ENVIRONMENT

Use of this device is allowed only in healthcare facilities prepared for endovascular procedures.

3.5. PATIENT TARGET GROUP

The target group are patients requiring endovascular procedures in peripheral arteries. No known data restrict the use of this device in patients of particular gender or race.
Before making a decision concerning procedure with the use of the guidewire, potential benefits and risks should be considered individually for every patient.

4. WARNINGS

- This device is designed for single use in a single patient only. Do not resterilize or reuse. Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse or resterilization may also create a risk of contamination of the product and cause patient infection including the transmission of infectious disease(s). Contamination of the product may lead to injury, illness or death of the patient.
- Do not use if the package is opened or damaged.
- Do not use this device after the expiration date given on the package label.
- Do not use if the labelling is incomplete or illegible.
- Do not withdraw the guidewire against the needle bevel in a way that could lead to contact with the sharpened end of the needle - it may damage and/or peel the polymer coating, as well as damage and/or shear off the tip of the guidewire.
- Do not use in fully occluded vessels.
- Do not advance, withdraw or move the guidewire if there is unnatural resistance.

5. PRECAUTIONS

- The procedure must be carried out after adequate preparation of the patient in a healthcare facilities prepared to treat complications after endovascular procedure, in accordance with current national and global guidelines.
- All manipulations of the guidewire in vessel should take place under fluoroscopy.
- Avoid techniques and movements that could have kinked or tangled the guidewire.
- Flush the guidewire in the protective hoop with heparinized normal saline solution before use.

- Do not use excessive force while introducing, manipulating and removing the device. If resistance is felt, check the possible cause of resistance before deciding to continue the procedure.
- If the guidewire gets trapped / blocked in a vessel (e.g. in a small branch or stenosis), do not force the guidewire.
- Do not use a metal torquer with the polymer guidewire with the hydrophilic coating. A metal torquer may damage the guidewire.
- Do not expose the guidewire to alcohol, antiseptics or other solvents, as they may damage the coating.
- The patient should be given all information about the procedure and the correct conduct during and after the procedure.

6. HOW SUPPLIED

6.1. CONTENT OF THE PACKAGING

One (1) guidewire in a protective hoop, in a pouch, packed with the Instructions for Use in a unit box.

6.2. STERILITY

This product is supplied sterilized with ethylene oxide gas in a pouch. Only the content of the pouch should be considered sterile. The device is only sterile if this packaging is not opened or damaged.

7. HANDLING AND STORAGE

Store at room temperature in a dry place, in the unit box, as supplied.
Do not expose to temperatures outside the range: 10 ºC ÷ 30 ºC.

8. DISPOSAL INSTRUCTIONS

The used product shall be treated as medical waste.
After use, dispose the product and packaging in accordance with healthcare facility, administrative and/or local government policy.

9. WARRANTY

If delivered product is damaged or has any other defects, please inform the manufacturer and keep the device with original packaging.

10. OPERATIONAL INSTRUCTIONS

Balton sp. z o.o. shall not be liable for any direct, incidental or consequential damages resulting from the misuse of this product.

1. Select the version / size of the guidewire suitable for the device it is to be used with.
2. Check the primary packaging (pouch) for possible damage and expiry date.

If there is a suspicion that sterility may be compromised and/or the expiry date has been exceeded, it must not be used.

3. Open the pouch and take out the guidewire in the protective hoop.
4. Flush the guidewire in the hoop with heparinized normal saline in order to activate the hydrophilic coating.
5. Remove the guidewire from the hoop and check if the guidewire is not bent, kinked or damaged.

If there is a suspicion that the device is damaged, it must not be used.

6. Straighten the guidewire tip with the provided straightener.
7. Place the guidewire in a vascular access device and gently advance towards the desired position.

Do not use excessive force when inserting the guidewire. If any resistance is encountered during insertion, withdraw the guidewire partially, twist slightly and try to gently advance again.

Remember to leave a sufficiently long part of the guidewire outside the vessel for easier maneuvering and to prevent embolization by uncontrolled displacement of the guidewire in the vessel.

Do not withdraw the guidewire against the needle bevel (Fig. 3.) - it may damage and/or peel the polymer coating, as well as damage and/or shear off the tip of the guidewire.

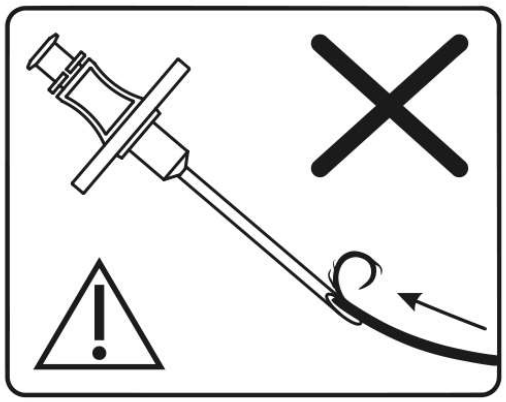

Fig. 3. Damage of the polymer coating

8. Remove the guidewire once after completing the procedures that required its use.

SYMBOLS GLOSSARY

CE	CE mark	MD	Medical device
UDI	Unique device identifier		Manufacturer
	Date of manufacture		Use-by date
REF	Catalogue number	LOT	Batch code
	Consult instructions for use or consult electronic instructions for use		Do not use if package is damaged and consult instructions for use
	Caution	STERILE EO	Sterilized using ethylene oxide
	Do not resterilize		Do not re-use
	Single sterile barrier system		Single sterile barrier system with protective packaging outside
	Non-pyrogenic		Keep away from sunlight
	Fragile, handle with care		Temperature limit
Not made with natural rubber latex	Not made with natural rubber latex	n	n units per package
	Keep dry		Recyclable packaging material
GW	Guidewire length	Ø GW	Guidewire diameter
F GW TYPE	Guidewire stiffness - FLOPPY	MS GW TYPE	Guidewire stiffness – MEDIUM STIFF
S GW TYPE	Guidewire stiffness - STIFF	TIP TYPE	Tip type – ANGLED
TIP TYPE	Tip type – STRAIGHT		