nio PEDIATRIC

Intraosseous Device

INSTRUCTIONS FOR USE

Instructions for use REF NIO-P

Single Use Automatic Intraosseous Device for pediatrics

Do not use if package is damaged

+10° +22°

Non – Pyrogenic

CE 2460 FDA CLEARED

℞ Only

STERILE R

Not made with natural rubber latex

PERSYS MEDICAL

Ver. 6 301700612

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* X marks Tibial Tuberosity

Illustrations will be followed by instructions

ENGLISH

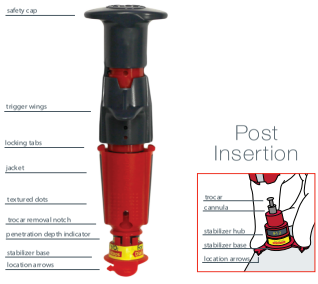
RECOMMENDED NEEDLE PENETRATION DEPTH:

Age	Proximal Tibia
9-12 years	18mm
3-9 years	Adjust to 14mm

1. Always wear gloves during the insertion procedure. Disinfect the skin at the injection site following institutional protocols. Open pack and remove the NIO-P.
2.Patients 9-12: The device is ready to use.
Patients 3-9: Dial the red stabilizer base until it stops.
3. Place the designated location arrow (R for patient's right leg, L for patient's left leg) on the prominent aspect of the Tibial tuberosity with the location arrows pointing upwards towards the knee and parallel to the long axis of the tibia. This aligns the device so the insertion site is medial to the Tibial tuberosity).
4. Hold the device by the textured dots and unlock it by rotating the safety cap 90° in either direction.
5. Note: Two-handed control should be maintained throughout the procedure. Place your non-dominant hand on the textured dots located on the lower part of the NIO-P and position the NIO-P 90° to the surface of the skin at the insertion site. Place the palm of your dominant hand over the safety cap and press the device against the skin. While maintaining downward pressure, pull the trigger wings upward. This action will activate the device.
6. Secure the stabilizer base against the patient and separate by lifting the device upwards.
7. Hold the red stabilizer hub in place while pulling out the trocar. The trocar removal notch on the distal end of the NIO-P can be used to assist in removing the trocar from the cannula. Place the trocar into a sharps container.
8. If indicated, aspirate bone marrow. Always confirm successful needle placement per your protocol. **Note: By holding the stabilizer hub, maintain stabilizer position when connecting / disconnecting any luer lock line / syringe from cannula.**
9. After confirming placement, affix the stabilizer base to the limb. It is recommended to use the NIO Fixation to affix the stabilizer base. Connect any standard infusion set. If the port is open, cover the insertion site with a sterile occlusive dressing.
10. REMOVAL INSTRUCTIONS: Remove the cannula and needle stabilizer base by pulling upward. Dispose using a biohazard container. Cover the insertion site with a sterile occlusive dressing.

NIO DESIGN

The NIO-P is an automatic, single use, spring-loaded IO device with a double safety mechanism, and location arrows for easy site identification maximizing caregiver and patient safety. Post activation, the needle stabilizer base firmly secures the needle.



INDICATIONS FOR USE:

The NIO-P for Pediatrics is intended to provide intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients in age 3-12 years old.

RECOMMENDATIONS:

• To ensure proper penetration, use the NIO-P in accordance with the location arrow's indication.
• Follow the directed method to set pentration depth, but it is essential to correctly assess the most effective penetration depth according to body habitus.
• Reassess IO site immediately after step 8 (confirm needle placement).
It is recommended to frequently monitor the limb every 10 minutes for the first half hour or longer after beginning of drug administration.
• Use a pressure bag for optimal infusion rates.
• Continue to monitor extremity for complications on a regular basis, especially pre and post infusion. Prior to drug administration, the needle should be verified for placement and patency by confirming its stability in the bone. Bedside Doppler ultrasonography may be useful to ascertain IO placement and flow.
• For conscious patients, consider local anesthesia such as lidocaine per institutional protocols.
• The IO catheter should be removed within 24 hours (depending on protocols). Needles should be removed once permanent venous access is established.
• Carry backup supplies of critical medical devices whenever possible.

⚠ WARNINGS:

• Do not aim the NIO-P toward the joint space or epiphyseal plate. • Discontinue infusion if any signs of infiltration are apparent, including tissue swelling around the insertion site. • The NIO-P contains sharp parts that should be disposed of in an appropriate container for disposal of medical biohazard waste. • The use of the NIO-P is restricted to skilled, authorized medics, nurses, paramedics and doctors who are trained to use the device. • Do not use if package is damaged. • The device must not be reused or re-sterilized. Reusing this disposable device might lead to infection, mechanical failure, or harm to the operator and/or patient. • When using any intraosseous device, the possibility of air embolism exists. • Metal needles are not MRI compatible. • Metal needles may cause scatter artifacts on computed tomography (CT) scans • The safe use of the NIO-P in patients with Osteoporosis, Osteopetrosis, Osgood-Schlatter, or other Tibial bone pathology or deformity has not been proven. These conditions may obscure landmarks of the tibia • Caution: This device is to be used on the order of and by a licensed physician or licensed practitioner. Rx Only

RECOMMENDED STORAGE CONDITIONS:

• The NIO-P device should be stored at 10–22 C°.
• The packages should be handled with care when placed in a storage room.

CONTRAINDICATIONS

Do not use the device if any of the following are present: • Skin infection at the site location • Tumor • Abnormalities of bone strength (e.g. osteogenesis imperfecta, osteopetrosis, osteoporosis) • Osgood-Schlatter disease • Deformation of insertion site • Previous intraosseous insertion/failure on the same bone within the last 48 hours • Previous orthopedic procedures near the insertion site • Fracture of the bone within the same extremity or the selected bone for insertion • Inability to locate anatomical landmarks or excessive tissue