BIG

SIMPLY SAVING LIVES

PEDIATRIC

BONE INJECTION GUN

RED - 18 GAUGE NEEDLE

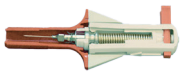
INSTRUCTIONS FOR USE

1. Palpate and mark penetration site.
   Ages 0-6:
   From tibial tuberosity, slide finger 0.5 inch medially and 0.5 inch distally. Remember to work away from the growth plate.
   Ages 6-12:
   From tibial tuberosity, slide finger 0.5-1 inch medially, and 0.5-1 inch distally. Remember to work away from the growth plate.

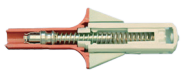
   Caution: make sure to avoid growth plate

2. Dial the red barrel to the patient's age in years. This sets the predetermined needle depth. The needle depth range is from 0.2 inch to 0.6 inch respectively.
3. Note that this is a two-handed procedure. Position the red barrel of the B.I.G. using the non-dominant hand at a 90 degree angle at the site. While maintaining patient contact, squeeze and pull the red safety latch out with the dominant hand. (For sterile technique, use sterile gloves).
4. Continue holding red barrel of the B.I.G. firmly with the non-dominant hand. While maintaining the 90 degree angle, position the dominant hand in a syringe-like fashion with the heel of the hand covering the top of the device. Trigger the B.I.G. with the dominant hand by pushing down with the heel of the hand. This is a two handed procedure; do not strike the top of the device or attempt to trigger the device with your thumb.
5. Remove the B.I.G. by carefully pulling upward with a slight side-to-side movement to clear the trocar hub.
6. Remove stylet / trocar from the cannula by pulling and rotating upward. The red safety latch can be used to assist in separating the trocar from the cannula.
7. Slide the red safety latch around the base of the needle. Tape the red safety latch to the skin to stabilize the needle.
8. For confirmation of successful needle placement, attempt to aspirate. If a lab specimen is desired, aspirate 2cc to 5cc of bone marrow. Flush with up to 10cc of NaCl or per your protocol. Connect any standard extension set or stopcock for infusion.

B.I.G. NEEDLE & SPRING DESIGN



A. Before the B.I.G. is triggered, the spring is coiled under pressure and is held by red safety latch to prevent misfiring.



B. After the red safety latch is removed and the B.I.G. device is triggered under direct pressure, the spring is released and drives the needle.
   Note: Exit hole at the end of barrel is "off center" as a safety feature.

RECOMMENDED NEEDLE PENETRATION DEPTHS: (PEDIATRIC - RED, 18G NEEDLE)

Age:	Proximal Tibia
Infants 0 - 3 years	0.2 - 0.3 in (0.5 - 0.7 cm)
Children 3 - 6 years	0.4 - 0.6 in (1.0 - 1.5 cm)
Children 6 - 12 years	0.6 in (1.5 cm)

RECOMMENDATIONS:

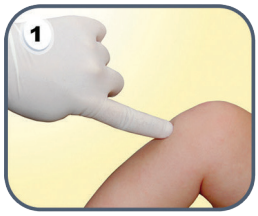
1. Reassess IO site immediately after step #8.
2. Carrying backup supplies of critical medical devices is an advisable medical protocol.
3. To produce optimal flow rates, the use of a pressure cuff is recommended.
4. Site skin preparation guidelines should follow the same as conventional IV access or per protocol.
5. For conscious patient, consider local anesthesia.

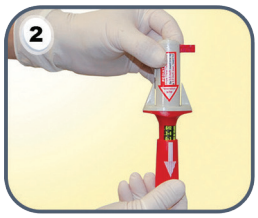
INDICATIONS FOR USE:

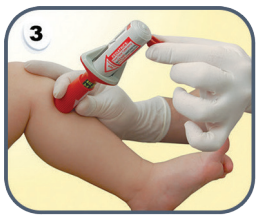
The B.I.G Bone injection Gun for Pediatrics is intended to provide intraosseous access in the proximal tibia, as an alternative to IV access, during emergencies. The device is for use in pediatric patients up to 12 years of age.

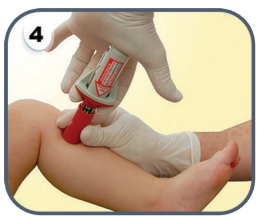
REMOVAL INSTRUCTIONS:

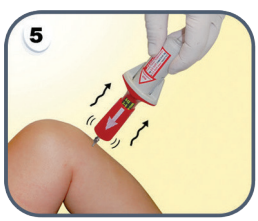
Upon completion of the procedure, use the red safety latch to remove the cannula. Place the square portion of the latch around the square portion of the hub and pull upward while twisting.

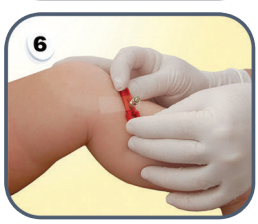


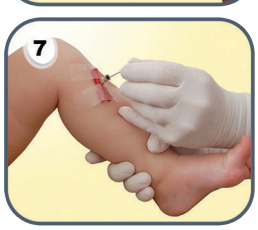


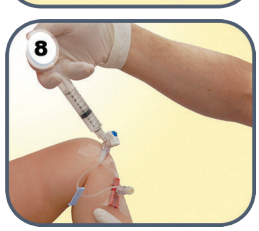












WARNINGS:

1. Intraosseous access is an alternative to standard or conventional intravenous access and is not recommended to be used for periods exceeding 24 hrs.
2. The use of the B.I.G. is restricted to skilled authorized medics, nurses, paramedics and doctor who were trained on the device.
3. Discontinue infusion if any signs of infiltration are apparent, including tissue swelling around the insertion site.
4. When using any intraosseous device, the possibility of air embolism, fat embolism, fractions of targeted bone, infections, and extravasation exists.
5. The safe use of the B.I.G. in patients with osteoporosis, osteopetrosis, Osgood-Schlatter disease, or other bone pathology or deformities has not been proven. These conditions may obscure landmarks.
6. The B.I.G consists of a metal needle and is not MRI compatible.
7. The B.I.G consists of a metal needle, which may cause scatter artifacts on computed tomography (CT) scans.

CAUTIONS:

1. Do not aim the B.I.G. toward the joint space or epiphysial plate.
2. The B.I.G. device is sterile and for single use only. Do not reuse or resterilize the device.
3. The B.I.G. device contains sharp parts that should be placed in a container for the disposal of medical biohazard waste.

CONTRAINDICATIONS:

- Skin infection at the site location
- Tumor
- Osteogenesis Imperfecta
- Osteoporosis
- A second attempt following previous IO insertion/failure on the same bone
- Previous orthopedic procedures near the insertion site
- Fracture of the bone with in the same extremity or selected bone for insertion

WARNINGS ON RE-USE OF THIS DISPOSABLE MEDICAL DEVICE:

Reusing this disposable device might lead to infection, mechanical failure and harm to the operator and/or patient

	Manufacturer	STERILE R	Sterilized using irradiation		Keep away from sunlight
	Do not use if package is damaged		Do not re-sterilize		Keep dry
	Do not re-use	Rx Only	Caution: Federal law restricts this device to sale by or on the order of a physician	LOT	Batch code
	Fragile, handle with care	REF	Catalogue number		Use-by date
	Non pyrogenic	MR	MR (Magnetic Resonance) unsafe		Consult Instructions for Use

NOT MADE WITH NATURAL RUBBER LATEX

PerSys Medical®

PART OF SAFEGUARDMEDICAL

WaisMed, Ltd.
10 Amal St. Afek Industrial Park, Rosh Ha'Ayin 4809234 Israel
Tel: +972-9-9517-444 | Fax: +972-9-9517-666

safeguardmedical.com
infoIL@safeguardmedical.com | vigilanceIL@safeguardmedical.com

PEDIATRIC REF WMBIG-C2

301700521 Rev. 1.0, 2022-10-13