ARGON
MEDICAL DEVICES

Instructions for Use

ARTHROGRAPHY TRAY

Intended Use:
The Arthrography tray is intended for the injection of contrast dye into the joint (eg. shoulder, knee, wrist, ankle).

Contraindications:
This tray should be used by a physician familiar with the possible side effects, typical findings, limitations associated with Arthrography. The following are known contraindications with use of this product:

- Reflex sympathetic dystrophy
- Avascular necrosis of bones adjacent to the affected joint
- Coagulopathy

Cautions:
- **Rx Only**: Federal Law (USA) restricts this device to sale by or on the order of a physician. Read instructions prior to use.
- The Arthrography tray was designed, tested and manufactured for single use only.
- Do not use the contents if package is open or damaged.
- Do not reuse, reprocess or re-sterilize. Reuse or reprocessing has not been evaluated and may lead to product failure and subsequent patient illness, infection, or other injury.
- Verify the integrity of all items in the tray before use. Do not use if an item appears damaged.

Warnings:
- These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.
- Do not force the shield over the needle, as it may penetrate the shield causing injury.
- To avoid needle breakage, do not attempt to straighten a bent needle; discard and complete the procedure with a replacement needle.
- Do not reshield used needle.

Potential Complications:
Arthrography should not be attempted by physicians unfamiliar with the possible complications. Possible complication may include, but are not limited to the following:

- Infection in the joint
- Joint Pain and/or Damage
- Allergic reaction to the contrast dye
- Vasovagal reactions

How Supplied:
The Arthrography tray is supplied sterile by ethylene oxide gas. It is intended for single use only. Do not use the device if package is open or appears to be damaged or defective. The device has no components made of natural rubber latex.

Preparation and Instructions for Use:
1. Position the patient.
2. Open hospital wrap using sterile technique and position towel under patient.
3. Prepare puncture site with ChloraPrep®. ***Note:*** *Detailed instructions enclosed for the use of ChloraPrep®.* The prep well provided may be used with desired antiseptic.
4. Drape patient.

20-1100-03/0615A

5. Raise skin wheal using the hypodermic needle and the 10 ml syringe containing local anesthetic.
6. Fill remaining 10 ml syringe with desired dose of aqueous contrast medium. Use 18 G x 1½" needle to withdraw media from vial.
7. A 1½" hypodermic needle is provided for insertion into the joint. If desired, remove excess synovial fluid through needle using the 10 ml syringe.
8. Inject contrast media into the joint capsule. If using a fluoroscope, the 20" extension tube may be used to avoid unnecessary exposure to the fluoroscope beam. ***Note:*** *Contrast media is not provided in this tray*.
9. The 60 ml syringe may be used to inject gas for double contrast arthrography.
10. After injection of contrast media, withdraw needle.
11. At completion of procedure, cover puncture site with bandage.

Disposal:

After use, this product may be a potential biohazard. Handle in a manner which will prevent accidental puncture. Dispose in accordance with applicable laws and regulations.

Storage:

Store at standard ambient temperature.

Symbols:

STERILE EO	Sterilized using Ethylene Oxide		Use Before Date		Do not Re-Sterilize	RxOnly	Prescription Use Only
	Consult instructions for use		Single Use Only	REF	Catalogue number	PHT DEHP	Contains phthalate: DEHP
	Do Not Use if Open or Damaged	LATEX	Not made with natural rubber latex	LOT	Batch Code		Manufacturer

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