

NO-NEEDLE JET INJECTOR PODIATRY PRESENTATION



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Introduction

Certainly most physicians can put a needle into a patient's tissues with minimal pain. However, it is not so much the pain from the needle that bothers patients, IT IS THE NEEDLE ITSELF that patients fear. "Needle Phobia" is a real phenomenon that physicians contend with on a daily basis. Reducing this fear can make procedures easier and faster for both physician and patient.

1) Description of the MadaJet XL Podiatry Unit

The MadaJet XL Podiatry Unit is a fine precision instrument which functions as an injection device for local anesthetic agents into the skin. The first Podiatry MadaJet XL was announced more than 20 years ago and quickly became accepted by many progressive Podiatrists. By using this device, they were able to resolve the fears of patients who often put off going to the podiatrist for fear of "getting an injection."

The unique MadaJet XL Podiatric instrument has two (2) major applications in Podiatry:

- a. The injection of local anesthetic agents
- b. Injections of other various medicaments i.e. sclerosing agents, Vitamin B-12, aqueous Vitamin A and steroids for the treatment of various dermatological conditions

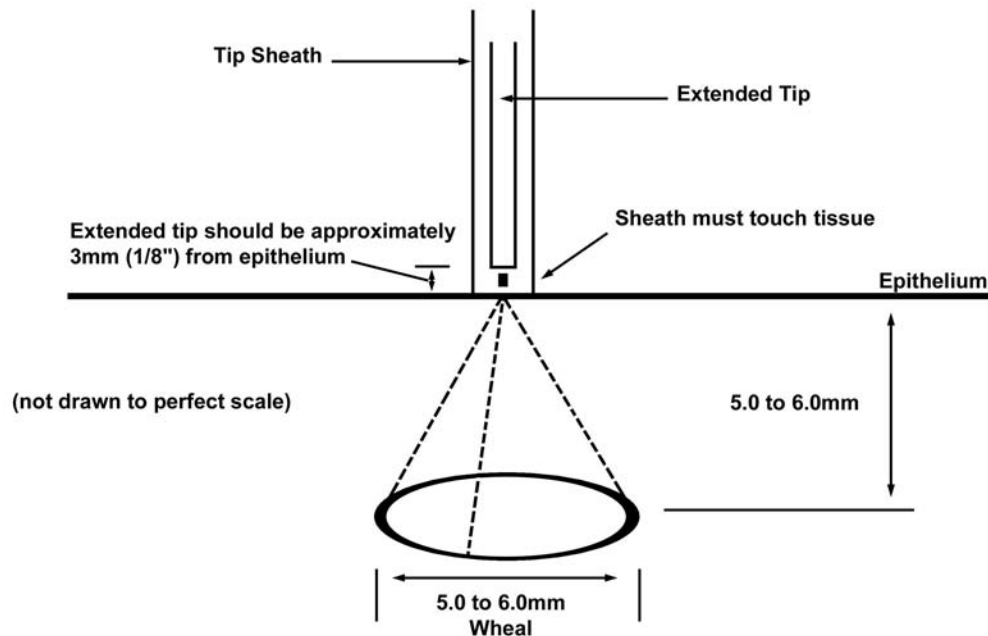
The physiological advantages of jet injections is that the podiatrist can provide effective anesthesia using small volumes of local anesthetic of at least a 2% concentration, with minimal patient discomfort compared to conventional needle and syringe techniques. When greater volumes of anesthetic agents may be required, the syringe and needle can be used and the patient is totally unaware of the experience, when the site of injection has been anesthetized in advance using the MadaJet XL.

Another advantage of jet injection technique is that a very small amount by volume (0.1 cc of 2% anesthetic) will provide unusually high levels of tissue anesthesia. This advantage results in the absence or minimal blood levels of any medication injected with the MadaJet XL.

The MadaJet XL requires at least 50% less volume of anesthetic to achieve the same level of anesthesia. This advantage is the result of the particle size of the anesthetic agent which enters the tissue. The normal volume per injection is only 0.1 cc, and although this may seem to be a small volume, with it unusually high levels of anesthesia can be accomplished. For example, 0.1cc of 2% Lidocaine injected at the base of the digit in four separate injections for a total of 0.4 cc can easily produce surgical anesthesia for four (4) hours or more. This will be discussed further under the Techniques Section. The advantage of using these small volumes of anesthetic agents even with epinephrine is that blood titers are almost impossible to attain and this is especially helpful when using epinephrine to localize the anesthetic agent.

The controlled depth of penetration of anesthetics or other aqueous medicaments in most soft tissues is illustrated by the following diagram. In contrast to "pooling" of medication by syringe/needle, MadaJet XL disperses the medication into the tissue in tiny droplets, producing almost immediate effect (about 1 millisecond) from the absorption by the myelin sheath covering nerve tissue. This effect can also be long-acting when required (3-4 injections).

Soft Tissue Penetration of Anesthetics and Aqueous Medicaments Injected with the No-Needle Jet Injector



2) Unique Features of the MadaJet XL

A) Extended Tips

The Podiatry MadaJet XL is available with Extended Tips varying in length from 3/4" (19.05 mm) to 6.5" (165.1 mm) and these lengths are selected by the physician according to the applications required.

To enhance safety, the MadaJet XL allows the Podiatrist to remove the tip between patients and replace it with another sterile tip. Two standard 3/4" (19.05mm) Extended Tips with sheaths are provided with each MadaJet XL and additional quantities can be purchased on request. The Extended Tips are removable and interchangeable between patient uses. They can be sterilized by autoclaving, cold sterilization and other normal sterilizing procedures. Each Extended Tip comes with a protective sheath which is normally placed gently on the tissues to be injected. The sheath should be left on the Extended Tips at all times, unless it is removed to change the tip.

B) The MadaJet XL Stand

This stand provides a place where the MadaJet XL should be kept between patients, and also when not in use during non-office hours. By placing 30-40 cc of the ready-to-use MadaCide Solution in the MadaJet XL stand, the head remains immersed in this Germicidal/Detergent Solution between patients or when the instrument is not in use.

C) MadaCide Solution

This is a government-licensed product and is classified as a Hospital Level Disinfectant/ Cleaner with synergistic formulas. MadaCide is ready-to-use. DO NOT DILUTE. This product is effective against Herpes, H.I.V., Coxsackie's Virus plus Mycobacterium tuberculi and many other pathogenic organisms. MadaCide is used to disinfect and clean the MadaJet XL. (Please see complete directions in the Care of the MadaJet XL.) MadaCide solution is provided with every MadaJet XL with the possible exception of some units shipped overseas) and comes in 22 oz bottle with spray attachment and gallon sizes.

D) Head Assembly

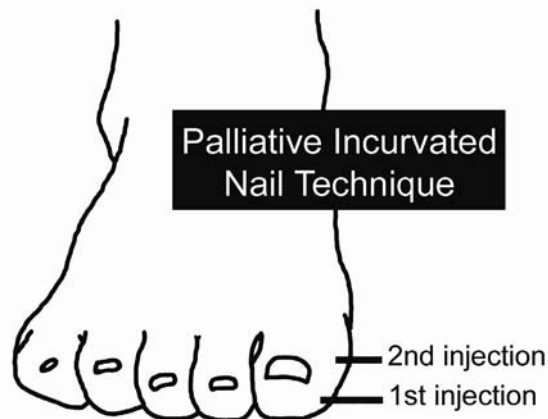
The fill chamber mounted on the head assembly will hold up to 4.0 cc (ml.) of any aqueous medication and can be filled by transferring the medicament desired from a multi dose vial into the fill chamber with a sterile syringe. Mixtures of medications can easily be made i.e., local anesthetics and various steroids. The minimal volume which should be put into the fill chamber is ½ ml. or cc. There are two (2) extra Pyrex fill chambers in the attractive carrying case.

3) Some Specific Uses of the MadaJet XL in Podiatric Procedures

The MadaJet XL podiatry device has been engineered and manufactured for the surgical and medical care of the foot. This model is made primarily for the Podiatric profession and is an indispensable instrument for all progressive and caring Podiatrists. It is the only American made instrument of its kind and fully guaranteed by its manufacturer, a company which has always supported this medical specialty. The MadaJet XL is a dependable jet injection device can be used to either prepare a site for virtually painless deep needle insertion, or in many cases it is more than adequate by itself in producing local or regional blocking.

A) Palliative Incurvated Nail Technique

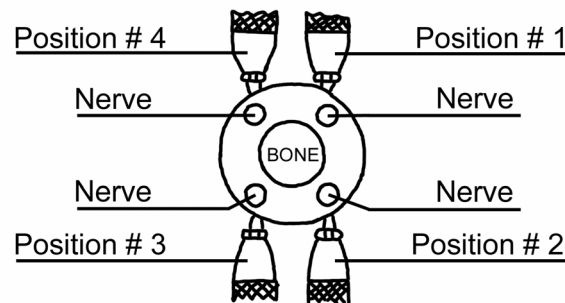
Podiatrists report that this procedure is especially useful with patients that are apprehensive. In this procedure, temporary relief or in some cases alleviation of the condition can be accomplished. Using 2% Lidocaine or other anesthetic (local) agents of this concentration in your MadaJet XL, inject at a site 2-3 mm lateral ad proximal to the angle of the nail base. Then with the MadaJet XL inject at a site approximately 10-12 mm from the anterior or distal portion of the digit on the same lateral or medial aspect. This should provide more than adequate anesthesia in seconds and is actually a modified block. Remove the hyperkerotic tissue in the sulcus and the nail spicule. If additional anesthesia is needed, simply inject directly into the sulcus with the MadaJet XL. This procedure should normally provide a pain free working area for 30-50 minutes. Then apply the disinfectant of choice, Merthiolate or beta-iodine, etc. dress wound etc. Frequently, the spicule can be elevated and sterile packing placed beneath the incurvation (see diagram).



B) Radical Removal (Evsion)

Two techniques with the MadaJet XL have been recommended to us by podiatrists:

- 1) Inject at the base of the proximal phalanx and use this painless site to provide deep needle insertion with your needle and syringe.
- 2) Total Digital Blocks with the MadaJet XL: this can be easily accomplished with the lesser digits, and may be more difficult with the hallux, however, this can be done after you have developed your techniques with the MadaJet XL. Procedure Recommended: By using the local anesthetic of choice i.e. 2% Lidocaine with or without epinephrine (1:100,000), inject into the area of the Dorsal, Medial and Lateral nerves as well as the plantar, medial and later all nerves. The sites of the four (4) injections should be into the web areas 2-3 mm proximal to the edge of the web. Four injections with a volume of only 0.1 cc per each injection or total of 0.4 cc, when done correctly, will provide complete surgical anesthesia for 3-5 hours duration. It is important however that each injection be made medially and lateral to the bone, NOT directly into the bone or ligament. This is often referred to the Letter "H" technique. The following diagram illustrates this technique.



Cross Section of Lesser Digit

It has also been indicated to us that when there is minimal fleshy tissue in the web area, this area can be increased both dorsally and on the plantar surface by pushing the tissues posteriorly to anteriorly with the thumb and first finger. When attempting the "H" technique on the Hallux, it may be necessary to give one or two more injections on the dorsum and dorsi-flex the hallux to inject under the dorsal tendon area with the MadaJet XL.

C) Posterior Tibial Blocks

Practitioners have told us that an injection with MadaJet XL and subsequent raised wheal will occur at the site of the tibial malleolus and the posterior tibial artery. A needle is then diverted at a 45 degree angle, and after aspirating so as to avoid the posterior tibial artery, 2 ml of 2% lidocaine is deposited. The needle is withdrawn to the dorsal skin wheal, directed medially in a closed "V" and an additional 2 ml of anesthetic is deposited. This procedure is repeated for the lateral tight "V".

D) Plantar Verrucae Procedure

Podiatrists have told us that this commonly observed condition can generally be handled with the MadaJet XL in several ways.

- 1) Excision: Surgical removal by curettage or punch method is preceded by 4 injections with the MadaJet XL placed around the lesion at 45 degree intervals or at 6-8 mm spacings. A total of 4

injections of 0.1 cc per injection should provide 2-3 hours of operative anesthesia. If the patient should complain of any sensation or even mild discomfort, injections with MadaJet XL directly into operative area recommended.

- 2) Medical Procedures: Introduction of various medications, anesthetics, sclerosing solutions, Vitamin B-12, etc., can be used directly into the lesions.

Note: A number of podiatrists have recommended that, before any procedure on the plantar surface begins, the foot should be soaked well in either MadaCide solution or the disinfectant/cleaner of the practitioner's choice, and the cornified epithelium be gently scraped or removed with a scalpel to allow the maximum penetration of the MadaJet XL injections.

- 3) Electrodesiccation: This requires using the same method as described above for introducing anesthesia.

E) Tenotomy, Tenectomy and Capsulotomy:

The MadaJet XL is directed on one side of the extensor tendon or the dorsum of the foot slightly distal to the articularum and an injection is made. This will generally permit a painless "snap" tenotomy with the use of a sterile #12 ASR blade or a sterile tenotomy scissor. If a tenectomy and capsulotomy is necessary, another MadaJet XL injection may be used and the needle and syringe injected through the wheal previously formed by the MadaJet XL.

F) Dermatological Procedures:

Frequently the patient presents various skin problems of which neuro dermatosis is a common observation. Practitioners have told us that such conditions as psoriatic lesions often respond quite dramatically to injections of steroids with the MadaJet XL. Three important advantages are present with this technique:

- 1) Small amounts by volume of the steroids are required
- 2) Elimination of considerable pain by needle and syringe technique is eliminated.
- 3) Blood titers or blood levels of steroids are extremely minimal or completely absent.

Note: A number of practitioners have told us that the steroid Celestone Soluspan, by Schering, is an excellent choice and a mixture by volume of 1/3 local anesthetic (2%) to 2/3 steroid mixed in the MadaJet XL has worked. Repeated weekly injections for the treatment of various skin disorders is normal and should be explained to the patient.

G) Calcaneus's Spur and Bursitis:

Direct injections with the MadaJet XL of anesthetic agents at the medial plantar border of the foot at the level of the brest of the heel, followed by deep needle insertion or infiltration of steroids combined with anesthetic agents.

H) Podiatrists Report that Other Procedures Using the MadaJet XL with Anesthetics are Possible:

1. Biopsies
2. Incision & Drainage
3. Emergency Suturing
4. Morton's Neuralgia
5. Digital Steroid Injections
6. Hallux Valgus Bursitis
7. Steroid Infiltration of Bunions

No-Needle Jet Injector

with Extended Tip

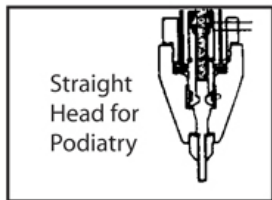
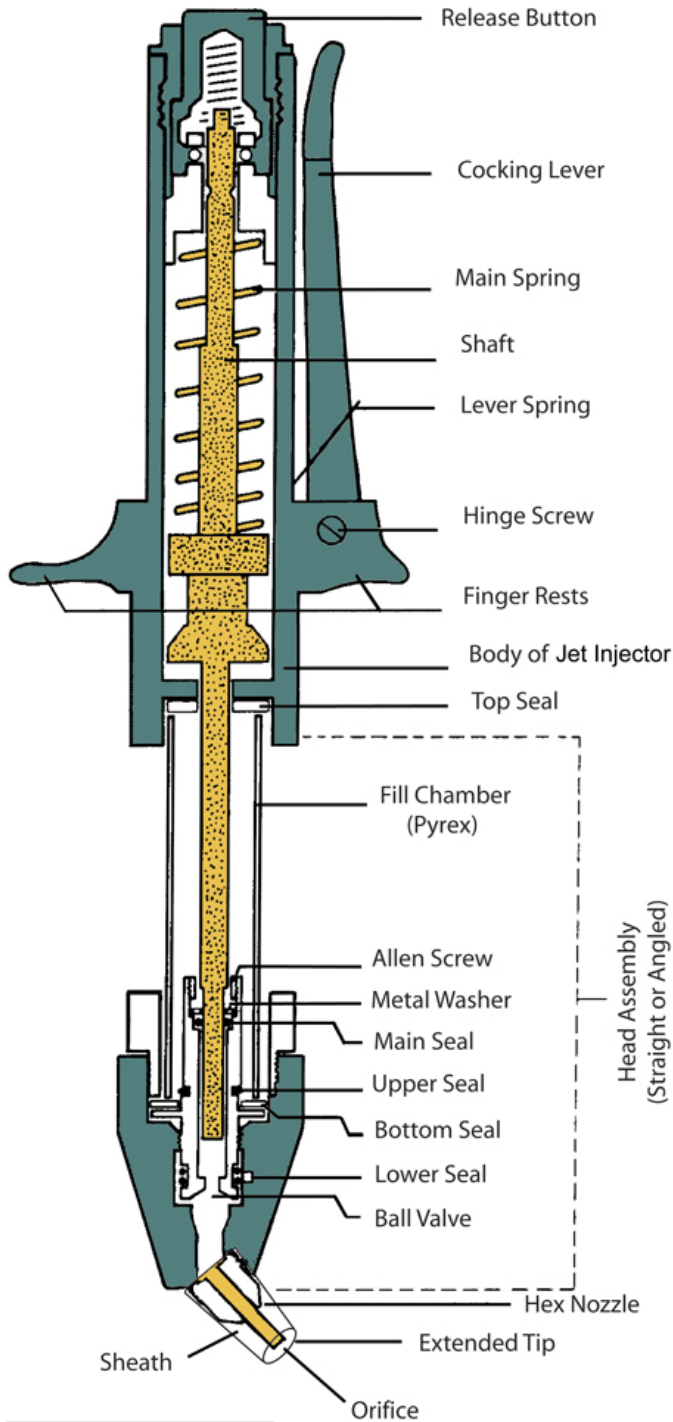
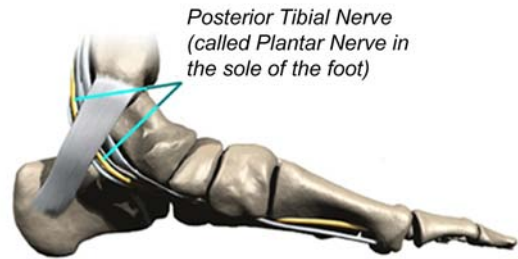
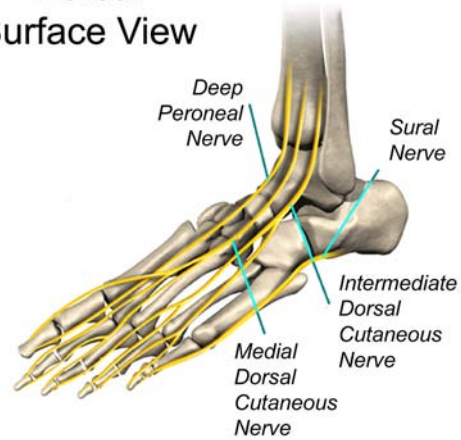


Diagram courtesy of Mada Medical

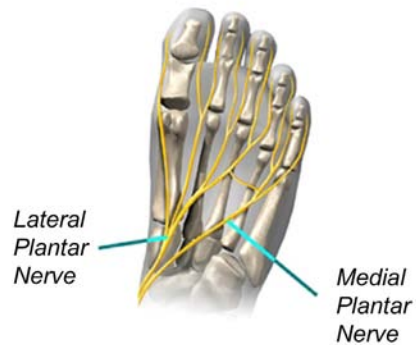
Medial Foot View



Dorsal Surface View



Sole / Plantar View



Care of the MadaJet XL with MadaCide Disinfectant/Cleaner

Please follow these simple directions.

- 1) Unscrew head assembly and pour spray approximately 3cc of ready-to-use Madacide into the glass fill chamber.
- 2) PRIME MadaJet XL by holding head assembly nose down and pushing MadaJet XL body in and out of the head assembly (2-3 times). This will force MadaCide out of the Extended Tip. Screw head assembly onto body.
- 3) Pour or spray enough MadaCide into the plastic holder to cover Extended Tip. Place MadaJet XL into the holder for a minimum of 10 minutes until ready to use (overnight or for extended periods).

Before Using Your MadaJet XL Podiatry Unit

- 1) Unscrew head assembly and empty MadaCide out of the fill chamber.
- 2) FLUSH out MadaCide by putting 2-3cc of anesthetic solution or sterile water into fill chamber.
- 3) PRIME MadaJet XL as above then empty the "flush" solution.
- 4) Put 1-3cc of anesthetic solution (2%) or medicament to be used into the fill chamber.
- 5) Prime 2-3 times. Screw head onto body, cock, and fire (see page 2 of manual).
- 6) Place MadaJet XL into holder.

NOTE: Between patients you may elect to change the Teflon[®] sheaths which fit over the Extended Tips. Additional quantities are available in packages of 30. These sheaths are reusable and may be autoclaved.

At the End of Each Day

- 1) Unscrew head assembly, empty out contents of fill chamber; follow directions 1-4 in first paragraph.

To steam autoclave or gas sterilization procedures the entire MadaJet XL follow normal sterilization procedures. Be sure to flush out all anesthetic solutions before proceeding.
DO NOT USE DRY HEAT OR CHEMICAL STERILIZERS.

Do not leave anesthetics in MadaJet XL overnight as this may cause brown staining or clogging of the Extended Tip. Change the MadaCide solution in the MadaJet XL holder at least twice a week, or as needed.

Trouble Shooting For:

- Loss of penetration (reduced levels of anesthesia).
- Unusual pain at the site of injection.
- Fuzzy jet stream 1-2" from the Extended Tip.

Do the Following:

- Probe small opening in end of the Extended Tip with stylet supplied in case (4-6 mm).
- Cock and fire MadaJet XL 2-3 times to ensure a proper fine jet stream. If you have an ultrasonic cleaner, place only the head assembly with Extended Tip in the unit. Use MadaJet XL solution in the ultrasonic cleaner for 10 minutes to provide disinfecting and cleaning action

If you have any problems, please call our office at 1-800-635-2452 or e-mail us at custserv@ameditech.com.