

7. Maak de spuit aan de luer-connector van de Quadra-Fuse\*/Quadra-Fuse\* ST naald vast, bevestig de juiste plaatsing van alle naaldpunten, open de klem op de verlengslang en injecteer de vloeistof. Sluit de klem na elke injectie. Een draaiing van 60 graden en opnieuw injecteren van vloeistof in het doelweefsel kan nodig zijn en is optioneel.

8. Na het voltooiën van de vloeistofinjectie trekt u de naaldpunten in de canule terug door de plunger helemaal in te trekken. Injectie van vloeistof in het weefseltraject bij het verwijderen van het instrument kan tot stand worden gebracht terwijl de punten helemaal ingetrokken zijn. Werp de Quadra-Fuse\*/Quadra-Fuse\* ST naald weg in overeenstemming met de richtlijnen van uw instelling nadat de procedure is voltooid.

\* *Quadra-Fuse is een handelsmerk van Rex Medical*



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**STERILE R**



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**P-4018-0166-00, Rev. D**

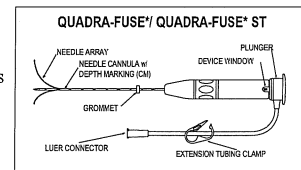
US PATENTS: 6,905,480; 7,087,040;  
 7,331,947; 7,344,518

**ENGLISH**  
**Quadra-Fuse\* / Quadra-Fuse\* ST**

Multi-Pronged Injection Needle  
 Reorder Code (Quadra-Fuse\*)  
 #4518-20SS (20cm) 4518-15SS (15cm) 4518-10SS (10cm)  
 Reorder Code (Quadra-Fuse\* ST)  
 #4218-20SS (20cm) 4218-15SS (15cm) 4218-10SS (10cm)

**Description and Intended Use**

Quadra-Fuse\*/Quadra-Fuse\* ST multi-pronged injection needle is an 18 gauge stainless steel disposable device designed for the infusion and aspiration of fluids. Quadra-Fuse\* needle includes 5 adjustable settings (tine array diameters of 1,2,3,4, and 5cm). Quadra-Fuse\* ST (short tip design) needle includes 2 adjustable settings (tine array diameters of 1 and 2cm).



Kit contents:

1. Quadra-Fuse\*/Quadra-Fuse\* ST multi-pronged injection needle
2. Skin Patch with 30 degree and 60 degree reference chart

These procedures should only be performed by physicians and staff familiar with the equipment and techniques involved.

The device has been sterilized by gamma (ISO EN552-A1) and is sterile unless the package is opened or damaged.

The package should be examined before use; if damaged, DO NOT USE.

The device is intended for single patient use only; DO NOT REUSE OR RESTERILIZE.

**PRECAUTIONS**

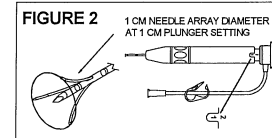
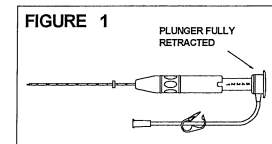
1. Always use standard sterile, aseptic technique.
2. Always flush Quadra-Fuse\*/Quadra-Fuse\* ST needle with sterile heparinized saline solution prior to use.
3. Do not use the device if there is evidence of mechanical damage or leaking.
4. Fill (prime) the device prior to use to minimize potential for cannula obstruction. Once the device is properly primed, be sure to close the extension tubing clamp.
5. Excessive force should never be used to place needle or prongs.
6. Excessive force should not be used to infuse or flush obstructed lumen. Do not use a larger syringe than 10ml (cc).
7. Be sure to confirm proper Quadra-Fuse\*/Quadra-Fuse\* ST needle position with proper imaging guidance (i.e. CT, US, Fluoroscopy).
8. Before needle cannula insertion (use), be sure to retract plunger completely. Needle prongs should be completely contained inside cannula prior to insertion.
9. As necessary, clean the needle array between deployments by rinsing the needle array in sterile heparinized saline solution or by gently wiping the prongs to remove excess tissue. Accumulation of excess tissue on the prongs may make array retraction difficult.
10. It is recommended that only luer lock (threaded) accessories and components be used with the Quadra-Fuse\*/Quadra-Fuse\* ST needle luer connector. Repeated over tightening of syringes will reduce connector life and could lead to potential connector failure.
11. Federal (USA) law restricts this device to be sale by or under the direction of physician.

**WARNINGS**

1. Infusion through Quadra-Fuse\*/Quadra-Fuse\* ST needle luer connector can only be initiated after all air is removed from the device.
2. Due to risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients. Sterile technique must be strictly adhered to during any handling of the device.

**INSTRUCTIONS FOR USE**

1. Remove the device from the package and retract plunger completely. Needle prongs should be completely contained inside cannula prior to needle insertion (Figure 1).
2. Flush and fill (prime) with sterile heparinized saline solution prior to use (priming volume is indicated on extension tubing clamp). Once the device is properly primed, be sure to close the extension tubing clamp.
3. Determine size of the target tissue using pre-operative imaging.
4. Determine optimal needle array diameter (cm). Adjustable needle array diameter Quadra-Fuse\* (1, 2, 3, 4 and 5cm)/Quadra-Fuse\* ST (1 and 2cm) is clearly indicated on plunger (Figure 2).
5. Insert and advance the cannula of the Quadra-Fuse\*/Quadra-Fuse\* ST needle into the tissue. Cannula

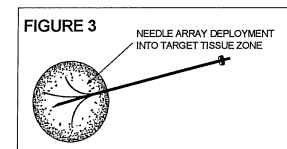


depth markings (cm) and grommet may aid in placement accuracy. Skin patch with 30 degree and 60 degree reference chart may assist in placement/deployment accuracy. Position the tip of the cannula at the target site using ultrasound, CT or other imaging guidance.

6. Deploy the needle prongs of the needle array within the target tissue by advancing the plunger with one hand, while maintaining the position of the cannula and handle with the other hand (Figure 3). It is important to keep the cannula stationary during array deployment. If the cannula moves during the deployment, the array will not fully deploy into the tissue.

7. Attach syringe to Quadra-Fuse\*/Quadra-Fuse\* ST needle luer connector, confirm proper positioning of all the needle prongs, open extension tubing clamp and inject fluids. Reclamp after each injection. A 60 degree rotation and re-injection of fluids into target tissue may be warranted and is optional.

8. Following completion of fluid injection, retract the needle prongs into the cannula by retracting the plunger completely. Injection of fluids into tissue tract upon device removal may be accomplished with needle prongs fully retracted. Dispose of the Quadra-Fuse\*/Quadra-Fuse\* ST needle in accordance with institutional guidelines after completion of the procedure.



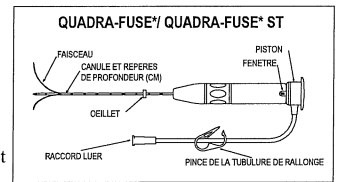
\* *Quadra-Fuse is a trademark of Rex Medical*

**FRANÇAIS**  
**Quadra-Fuse\* / Quadra-Fuse\* ST**

Aiguille d'injection à pointes multiples  
 Code de commande (Quadra-Fuse\*) :  
 4518-20SS (20cm) 4518-15SS (15cm) 4518-10SS (10cm)  
 Code de commande (Quadra-Fuse\* ST) :  
 4218-20SS (20cm) 4218-15SS (15cm) 4218-10SS (10cm)

**Description et indications**

L'aiguille d'injection Quadra-Fuse\*/Quadra-Fuse\* ST à pointes multiples est un dispositif en acier inoxydable de calibre 18, à usage unique, conçu pour la perfusion et l'aspiration de liquides. Le Quadra-Fuse\* comprend 5 réglages (diamètres de faisceau à pointes de 1, 2, 3, 4 et 5 cm). Le Quadra-Fuse\* ST (conception à embout court) comprend 2 réglages (diamètres de faisceau à pointes de 1 et 2 cm).



Contenu du kit:

1. Aiguille d'injection Quadra-Fuse\*/Quadra-Fuse\* ST à pointes multiples
2. Timbre transdermique avec tableau de référence pour 30 et 60 degrés

Ces procédures doivent être effectuées uniquement par un médecin et un personnel habitués à l'équipement et aux techniques employés. Le dispositif, stérilisé par rayons gamma (ISO EN552-A1), est stérile sauf si l'emballage est ouvert ou endommagé. Vérifier l'intégrité de l'emballage avant l'emploi ; s'il est endommagé, NE PAS UTILISER LE PRODUIT. Le dispositif est conçu pour un usage unique; NE PAS REUTILISER NI RESTERILISER.

**PRECAUTIONS**

1. Toujours observer une technique aseptique, stérile standard.
2. Toujours rincer l'aiguille Quadra-Fuse\*/Quadra-Fuse\* ST avec une solution saline héparinée stérile avant l'emploi.
3. Ne pas utiliser le dispositif en présence d'un dommage mécanique ou d'une fuite.
4. Remplir (amorcer) le dispositif avant l'emploi pour réduire le risque d'obstruction de la canule. Une fois que le dispositif est correctement amorcé, veiller à refermer la pince de la tubulure de rallonge.
5. Ne jamais appliquer de force excessive pour mettre en place l'aiguille ou les pointes.
6. Ne jamais appliquer de force excessive pour perfuser ou rincer une lumière obstruée. Ne pas utiliser une seringue supérieure à 10ml (cc).
7. Vérifier l'emplacement correct de l'aiguille Quadra-Fuse\*/Quadra-Fuse\* ST à l'aide d'un appareil d'imagerie médicale approprié (p. ex., tomographie assistée par ordinateur, échographie, fluoroscopie).
8. Avant d'insérer la canule de l'aiguille, s'assurer que le piston est tiré à fond. Les pointes de l'aiguille doivent se trouver entièrement à l'intérieur de la canule avant l'insertion.
9. Si nécessaire, nettoyer le faisceau de l'aiguille entre chaque déploiement en le rinçant dans une solution saline héparinée stérile ou en essuyant doucement les pointes pour en retirer l'excès de tissu. L'accumulation de tissu sur les pointes peut rendre difficile la rétraction du faisceau.





