Trigger-Flex_{Dart}

Depth Markings

A) 3 mmB) 3 mm

C) 3 mm

Cervical Procedure Overview ^{1, 2, 3}

The following information is intended to be used as a guide and should not be considered a substitute for surgical qualifications required to perform discectomy procedures or for training in the use of the Trigger-Flex[®] Dart.

Setting: Bipolar Turbo (Power Setting 10)

Recommendations:

- Only use the 16 gauge access needle supplied by elliquence, LLC. Recommended use of needle is one per spine level.
- Elliquence, LLC. always recommends a dry run prior to a live case or knowledge and experience of a cervical disc procedure.
- Please refer to the IFU packaged with the product for a complete list of warnings and precautions.

Step 1



Step 1: Placement of 16g Access Needle

Within full aseptic surgical conditions, first use the 2 finger approach to locate the targeted disc and location for access needle insertion.

2 finger approach





C) 3 mm

B) 3 mm

While using an anterior-posterior midline surgical approach insert the access needle to target the tip of the stylet to the posterior 1/3 of the disc nucleus by confirming proper positioning using A/P and lateral fluoroscopic views (as shown in fig 1). Remove the stylet.

Infuse approximately 1ml of saline without any pressure, making sure saline is filled to the top of the needle port.

Caution: To prevent insertion too close to the spinal cord and end plates observe Dart tip under fluoroscopic guidance and do not go further than the posterior 1/3 of the disc nucleus.



STEP 2: Initial Positioning of Trigger-Flex® Dart Insert the Trigger-Flex® Dart into the needle, while keeping the needle fixed until you reach the end of black depth marking C (as shown in fig 2).

Step 3

Step 2





STEP 3: Initial Positioning of 16g Access Needle While keeping the Trigger-Flex® Dart Device fixed pull the needle back to the anterior 3rd of the disc (as shown in fig 3).

Caution: The tip extends 10mm past the edge of the needle.

Lateral View

Step 4



Step 5





End Point

Step 6





Step 7



STEP 4: Ablation of Cavity A

Set the Bipolar Turbo Setting to 10. Keep the Needle in a fixed position. While at the initial positioning of the Trigger-Flex[®] Dart, activate the Dart while moving the Dart Anteriorly (out) and Posteriorly (in) within the beginning and end of the 3mm black depth marking A (shown in fig 4) to create cavity A. Do this at a rate of 1 second per stroke in each direction for a total of 5 strokes (total 5 seconds per cavity). Wait 5 seconds before moving to step 5.

Caution: Serious nerve injury or paraplegia may occur if the spinal cord or nerve root come into direct contact with the tip of the Dart device during activation. When performing ablation with the Dart device, stop the procedure if the patient complains of sudden onset of pain.

STEP 5: Ablation of Cavity B

Reposition: Pull the Trigger-Flex[®] Dart Anteriorly (out) until you reach the next 3mm depth marking B (shown in fig 5).

Activation: Keep the Needle in a fixed position. Activate the Trigger-Flex[®] Dart while moving the Dart Anteriorly (out) and Posteriorly (in) within the beginning and end of the 3mm grey marking B (shown in fig 5) to create cavity B. Do this at a rate of 1 second per stroke in each direction for a total of 5 strokes (total 5 seconds per cavity). Wait 5 seconds before moving to step 6.

STEP 6: Ablation of Cavity C

Reposition: Pull the Trigger-Flex[®] Dart Anteriorly (out) to the final 3mm black depth marking C (shown in fig 6).

Activation: Keep the Needle in a fixed position. Activate the Trigger-Flex[®] Dart while moving the Dart Anteriorly (out) and Posteriorly (in) within the beginning and end of the 3mm black marking C (shown in fig 6) to create cavity C. Do this at a rate of 1 second per stroke in each direction for a total of 5 strokes (total 5 seconds per cavity).

STEP 7: Removal of the Needle and Trigger-Flex® Dart

Caution: Do not withdraw the Trigger-Flex[®] Dart device while it is being activated.

Carefully remove the Needle and Trigger-Flex[®] Dart under fluoroscopic guidance. Keep finger tip pressure to aid in stopping any venous bleeding.

Energy Disbursement

Elliquence LLC. proprietary bipolar energy works by creating a Pure High Frequency RF field of energy that alternates flow between the tip to the outer Dart cannula.

This energy field has the ability to break down soft tissue in order to have a safe and controlled volume reduction, creating the cavity in the targeted area.

Ablation and Thermal Study

Fig. 7a



Nucleus Tissue Ablation:

Dissolving Targeted Tissue Volume. (As shown in Fig. 7a and 7b.)

When ablating the nucleus, the thermal spread is indicated below in the internal nucleus thermal study and thermal image. (As shown in Fig. 8.)

Fig. 8a



References:

formance has not been specifically established in all procedures.

2) TR 20160927-1

3) The following information is intended to be used as a guide and should not be considered a substitute for surgical qualifications required to perform discectomy procedures or for training in the use of the Trigger-Flex® Dart.

Warning and precautions:

A) Hazardous electrical output. This equipment is for use only by qualified personnel. B) Only elliquence supplied and/or approved accessories should be used to ensure proper operation. The elliquence generator and its accessories are identified with the manufacturer information and reference identification number for proper traceability. C) Read the instruction manual in detail before use.

D) Use of accessories or cables other than elliquence specified, as replacement parts for internal components, may result in increased emissions or decreased immunity of the elliquence RF generator. E) The coupling of any non-elliquence manufactured product, with an elliquence manufactured product invalidates all elliquence product warranties and all elliquence legal liabilities associated with such use.



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