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Urgent Field Safety Notice

ActiGait® Implantable Drop Foot Stimulator
NAS-2016-01
SIKKERHEDSINFORMATION vedrørende placering af ActiGait® implantatets stimulator

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Date: 2016.06.28
Attention: Alle trænede ActiGait® kirurger

Produktdetaljer:
Denne Field Safety Notice drejer sig om placering af ActiGait® Implantatet:

Order number	Cuff inside diameter
900203=W4	4.5 mm
900203=W5	5.4 mm
900203=W6	6.4 mm
900203=W	7.6 mm

Denne information omhandler alene nye implantationer – patienter der allerede er implanteret er ikke involveret.

Beskrivelse af problemstillingen:
Vi er tidligere blevet informeret om hændelser relateret til en ikke optimal placering af ActiGait® implantatets stimulator, i forhold til placering af manchetelektroden. Hvis den maksimale tilladelige afstand mellem manchetelektroden og stimulatoren ikke er fastlagt korrekt, kan det medføre et træk i manchetelektroden, som efterfølgende kan medføre skade på nervus peroneus.

Forholdsregler til brugeren:
Vi vedlægger vigtig sikkerhedsinformation vedrørende korrekt placering of ActiGait® implantatet – særlig vedrørende placering af stimulatoren. Neurodan A/S har revideret informationerne i kirurg-manualen i overensstemmelse med vedlagte information. Anbefalingerne er blevet opdateret for at give en entydig beskrivelse af, hvordan korrekt placering fastlægges.

Det er især vigtigt at fastlægge placeringen og foretage de nødvendige målinger på patienten med strakt ben.

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Denne sikkerhedsinformation er meddelt til og afstemt med relevante myndigheder.

Med venlig hilsen
Neurodan A/S

Bo Hammer Pedersen
Managing Director
Neurodan A/S

12.2.2 Drawing the Thigh Incision

The stimulator body can be placed in distal direction or proximal direction depending on the patient's height, anatomy and individual wishes (Figure 14). If the stimulator body is to be placed in proximal direction, measure a distance of 28 cm from the knee fold and mark it on the thigh (Figure 14, upper part). If the stimulator body is to be placed in distal direction, measure a distance of 24 cm from the knee fold and mark it on the thigh (Figure 14, lower part). All measurements must be performed with a fully extended leg.

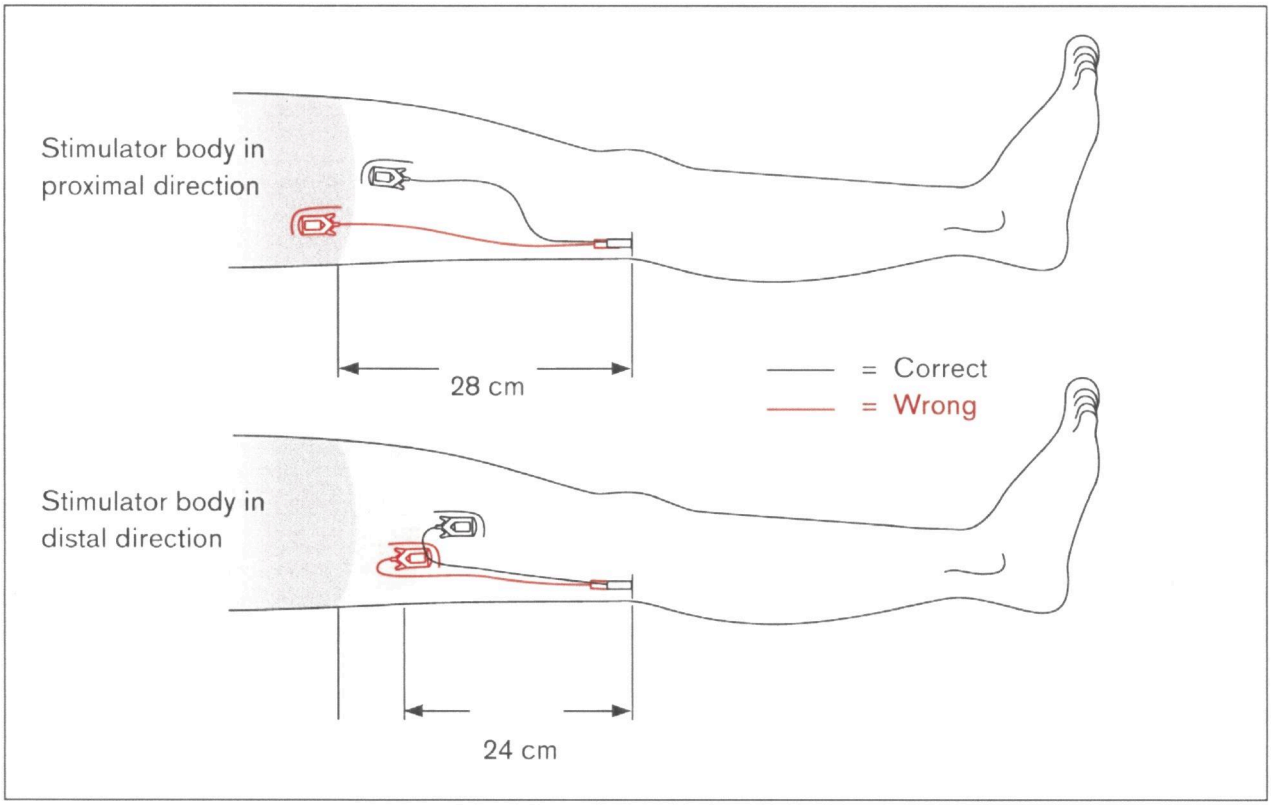

Figure 14: Limitations of the permitted area for placing the stimulator body in the proximal direction.

The distance between the cuff electrode and the stimulator body must lead to a slack, tension-free electrode cable path.

With the distal/proximal marking described above (Figure 14) combined with the anterior/posterior marking (Figure 12) made before the surgery, it is now clearly marked in which area the stimulator body can be placed (Figure 15).

Place a demo implant on the patient's leg to find the best position for the stimulator body, to achive a slack, tension-free electrode cable path. Make sure that the stimu-

lator body is placed within the markings previously made and that the cuff electrode is placed as close to the knee fold as possible. The electrode cable should follow a straight path from the cuff electrode to the 12 cm mark, and then progress in a smooth curve over the biceps femoris muscle up to the stimulator body (Figure 15).

Draw the thigh incision. The incision length and location should allow the stimulator body to be fixed into place by stitching it to the fascia (see section 12.14 on page 52). The incision should not cross neither the electrode cable nor the stimulator body, and it should give ample room for fixation.

The surgeon should consider positioning of the stimulator body (anteriorly-posteriorly, distally-proximally, and rotationally) by assessing the individual anatomy of the thigh (muscle atrophy and amount of subcutaneous adipose layer).

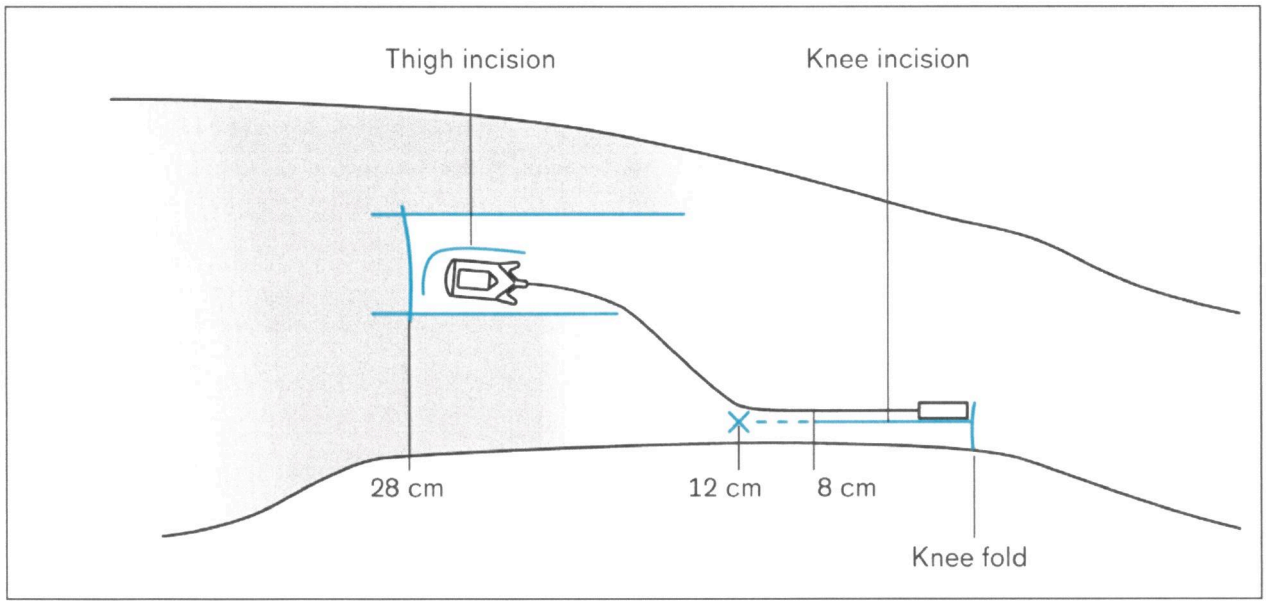

Figure 15: Drawings on the patient. Be sure that the knee fold, the two incisions and the 12 cm mark, to guide the tunnelling, are clearly marked before proceeding.