INTRODUCING NEEDLE

Instructions for Use

Healthcare Professionals

UNEEG™ medical

1. PRODUCT DESCRIPTION

The Introducing Needle is a sterile (electron beam radiation procedure), single-use specialised needle intended to be used for surgical insertion of the UNEEG™ SubQ implant. The product is available in two variants, in order to accommodate the two sizes of the UNEEG™ SubQ implant.

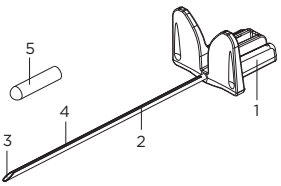
A summary of safety and clinical performance may be found on Eudamed through the European website (**www.ec.europa.eu/tools/eudamed**) or at the manufacturer website (**www.UNEEG.com**).

1.1 PRODUCT VARIANTS

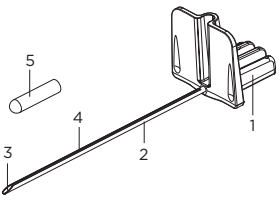
PRODUCT NAME	CATALOGUE NUMBER	DESCRIPTION
Introducing Needle	20001	Size 8
Introducing Needle	20000	Size 10

1.2 DESCRIPTION OF COMPONENTS

Introducing Needle, Size 10



Introducing Needle, Size 8



NO.	NAME	DESCRIPTION
1	Handle	Facilitate grip on Introducing Needle
2	Needle	Contains and protects the implant during implantation
3	Needle Tip	Distal end of Introducing Needle
4	Slot	Groove in needle to facilitate mounting of the implant in the Introducing Needle
5	Protection Cap	Protects the needle tip during transport and storage. Remove before use.

1.3 COMPATIBILITY

INTRODUCING NEEDLE VARIANT	COMPATIBLE UNEEG™ SUBQ VARIANT
20001 Introducing Needle, size 8	20100 UNEEG™ SubQ, size 8
20000 Introducing Needle, size 10	20101 UNEEG™ SubQ, size 10

2. INTENDED PURPOSE

2.1 INTENDED USE

The Introducing Needle is intended for subcutaneous insertion of the UNEEG™ SubQ implant.

2.2 INDICATION FOR USE

Patients ≥ 18 years to be implanted with UNEEG™ SubQ.

2.3 CONTRAINDICATIONS

- Patients at high risk of surgical complications, such as active systemic infection and haemorrhagic disease.
- Patients with infection at the site of device implantation.

Refer to the Instructions for Use for UNEEG™ SubQ for additional contraindications relating the implant.

2.4 WARNINGS

- Consider the anatomy of the patient's skull if using the full length of the product when implanting in the direction of the temple, as this may cause nerve damage (e.g., nervus facialis ramus temporalis).
- Do not attempt to clean and reuse the product as it is for single use only. Reuse of the product can cause contamination leading to infection.
- Do not use the product if the sterile packaging has been damaged or previously opened.

Refer to the Instructions for Use for UNEEG™ SubQ for additional warnings in relation to the implant.

2.5 PRECAUTIONS

- Do not use diathermy when the implant has been inserted, as this may damage the implant.
- Have a backup product readily available in case of malfunction.
- The product is intended for use by surgeons trained in the use of the product.

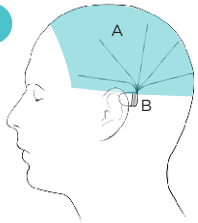
3. SIDE EFFECTS

Potential side effects in relation to surgical implantation procedure (non-exhaustive list):

- subcutaneous bleeding, haematoma, seroma, pain, headache, infection, discomfort, soreness, inflammation, swelling, irritation, itching, nerve damage, arterial injury, tissue damage and malposition of implant.

4. HOW TO USE

1



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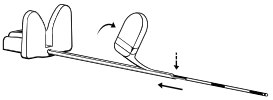
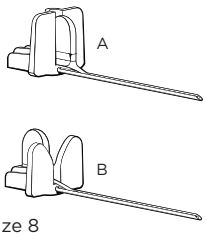


A Area (blue) of lead direction
B Position of housing

3



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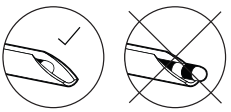

A Size 8
B Size 10

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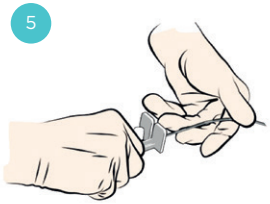

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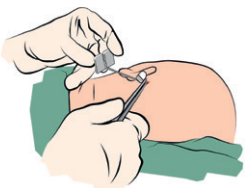

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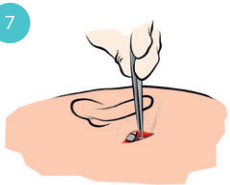

4.1 IMPLANT POSITIONING

The implant is placed subcutaneously, oriented in the direction where the electrical activity is intended to be measured. Various implantation positions are illustrated in **Figure 1**. The direction of the implant should be verified by the responsible healthcare professional prior to implantation.

4.2 IMPLANTATION

The implantation should be performed using local anaesthetic and as a sterile procedure.

4.2.1 PREPARATION

1. Select the size of the Introducing Needle based on the implant size.
2. Shave the hair behind the ear at the side of the head where the housing of the implant will be positioned.
3. Mark the position and direction of the implant.
4. The incision should be placed approximately 1 cm posterior to the housing near the hairline, and should be approximately 3 cm long to fit the length of the housing.
5. If the temporal-lobe position is chosen, mark the maximum distal placement, in order to avoid affecting nerve branches (e.g. nervus facialis ramus temporalis).

4.2.2 PROCEDURE

1. Inject local anaesthetic subcutaneously in the subgaleal space. It should cover the entire implantation site, including the full length of the implant (housing and lead).
2. Create a subcutaneous pocket, by blunt dissection, below the skin from the insertion point towards the ear. Make the pocket large enough to facilitate the implant (housing).
3. Diathermy can be used at this point for obtaining coagulation.
4. Unpack the implant and the Introducing Needle.
5. Mount the implant into the needle by placing the implant (lead) in the slot at the needle tip, as illustrated in **Figure 2**.
6. Pull the implant towards the handle. Make sure that all electrodes on the implant are inside the needle.
7. Place the implant (housing) in the handle of the Introducing Needle as illustrated in **Figure 3.** Make sure that the full length of the implant (lead) is placed inside the needle as illustrated in **Figure 4**.
8. If necessary, bend the Introducing Needle in the direction illustrated in **Figure 5** to fit the shape of the patient's skull.
9. Insert the mounted Introducing Needle into the subgaleal space from the incision's cranial corner, and push it along the skull in the direction indicated. Feel the tip of the Introducing Needle and follow it from the outside of the skin.
10. When reaching the desired position, withdraw the Introducing Needle in the same direction from which it was introduced. Ensure that the implant (lead) slides inside the slot of the needle, so that the implant stays in the desired position when Introducing Needle is withdrawn. This step can be supported with an atraumatic tool (see **Figure 6**).
11. Place the implant (housing) in the subcutaneous pocket as illustrated in **Figure 7**. If the implant (lead) is too long, it can be bent around the housing while sliding the housing into the pocket.

    WARNING: Diathermy is no longer allowed as it may damage the implant.
12. Complete the implantation by closing the incision posterior to the implant (housing).

5. SERIOUS INCIDENCE REPORTING

Per European Regulations: Report any serious incident that has occurred in relation to this product to the manufacturer and the competent authority of the EU Member State where the product was used.

6. DISPOSAL OF DEVICE

The product must be disposed of according to standard hospital procedures for waste handling.

7. TECHNICAL PRODUCT INFORMATION

Introducing Needle	**20001**	**20000**
Minimum bending radius	80 mm	80 mm
Storage and transport conditions		
Temperature	7 - 29 °C	7 - 29 °C
Humidity	30 - 60 %	30 - 60 %

8. SYMBOL EXPLANATION

Symbol	Description
	Manufacturer
	Date of manufacture
	Batch code
	Catalogue number
	Consult instruction for use
	Use by date
	Sterilized using radiation
	Do not re-sterilize
	Do not re-use (indicates a medical device that is intended for one use, or for use on a single patient during a single procedure)
	Do not use if package is damaged
	Temperature limits
	Humidity limits
	Medical Device
	Caution

UNEEG™ medical

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