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Disposable Urethral Electrode

Intended use
Embolization catheters to be used for the detection of biopotentials signals of pelvic floor and/or urethral sphincter muscle with recording, monitoring and stimulation equipment.

Instructions for use

- Check the catheter's smaller size (French (Fr.): 1 French is roughly equivalent to 0.33 mm in diameter, the smaller the number the smaller the catheter). Suitable sizes for children are from 8Fr. to 10Fr. for adults from 14Fr. to 20Fr.
- Before starting the procedure, clean the genital area with a mild soap, warm water and then patted dry.
- Do not use the urethral electrode if the pouch is damaged or if the product has expired.
- Open the sterile pouch and remove urethral electrode.
- Lubricate the catheter with a water-based lubricant, avoiding the contact between the lubricant and the electrode recording and stimulation area.
- Open the sterile pouch and the urethra as a normal catheter getting a stable interface between the electrode recording area and the external sphincter muscle.
- To maintain catheter position in place in bladder, inflate the balloon with a saline solution using a syringe. The following table inflation values:

Fr	Balloon size
6	1,5 ml
8	3 ml
10	5 ml
12-20	10 ml











- Create a gentle outward traction on the catheter maintaining the correct placement of the balloons against the internal urethral sphincter.
- Connect the urethral electrode cable with the equipment.
- Once the catheter is over, remove completely the saline solution from the balloon using a syringe without needle. Then gently remove the catheter.
- The device should be removed within 10 minutes at the end of the surgery as determined by a physician or other suitably qualified personnel who are familiar with this device.
- The stimulation electrical pulses should have a duration of ms and an intensity not exceeding 60-100 mA.
- During the catheter lubrication, avoiding the contact between the lubricant and the electrode recording and stimulation area.
- Only to be used by the clinical specialist.
- It is necessary for the user and/or patient to report any serious incident occurring related to the device, to the manufacturer and the competent authority of the member state where the user and/or patient is established.
- The environment of use is a hospital, specifically an operating room.
- Zakres zastosowania dla obu płci dla pediatrycznej populacji. The device does not have limitations of use related to age (from birth onward), gender, or weight. The clinical specialist will identify the correct size for the clinical need. There are no contraindications or warnings for pregnant or lactating women.

Warnings

- The urethral electrode is for single patient only. It is not designed for re-use. Use of the device and/or the single-use device expose patients and operators to a risk of cross contamination.
- Gloves must be worn by the operator during the catheterization to protect himself from infection and to avoid infection in the patient.
- Do not re-sterilize.
- Do not handle the catheter with sharp instruments.
- The device should be removed within 10 minutes at the end of the surgery as determined by a physician or other suitably qualified personnel who are familiar with this device.
- The stimulation electrical pulses should have a duration of ms and an intensity not exceeding 60-100 mA.
- During the catheter lubrication, avoiding the contact between the lubricant and the electrode recording and stimulation area.
- Only to be used by the clinical specialist.
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Contraindications and warnings for pregnant or lactating women

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Jednorazowa elektroda do cewki moczowej

Przeznaczenie
Elektroda jednorazowego użytku są przeznaczone do wykrywania sygnałów biopotencjalnych z wykorzystaniem sprzętowania służącego do zapisywania, monitorowania i stymulacji dla mnióska dna miednicy i/lub mięśnia zwężacza cewki moczowej.











Przeznaczenie
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- Wybrać odpowiedni rozmiar cewnika (skalę French (Fr.): 1 French odpowiada około 0,33 mm średnicy cewnika - nie zmieniać skali, tym mniejszy cewnik, tym mniejsze uszkodzenie tkanek i/lub ryzyko zakażenia).
- Przed rozpoczęciem zabiegu oczyścić okolice narządu moczowego ciepłą wodą z dodatkiem łagodnego mydła, a następnie osuszyć.
- Nie używać elektrody do cewki moczowej, jeśli opakowanie jest uszkodzone lub jeśli minął termin ważności wyrobu.
- Przed rozpoczęciem zabiegu należy sprawdzić, czy elektroda jest przeznaczona do użytku u danej populacji.
- Naznaczono zakresy lubrykacji na białej wodzie, unikając jej kontaktu z częścią elektrody służącą do rejestracji/stymulacji.
- Wykonując elektrody do cewki moczowej, tak jak standardowy cewnik, zwracając uwagę na czystość cewki moczowej.
- Nie dokonywać naprawy cewki moczowej służącej do rejestracji i stymulacji, ponieważ zamierzają one służyć jednemu pacjentowi.
- Abdy utymać cewnik w odpowiednim opakowaniu, napełnić białką rozczynem soli fizjologicznej za pomocą strzykawki bez igły. Ponizsza tabela zawiera wartości napięciowania białki:











Fr	Rozmiar białki
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8	3 ml
10	5 ml
12-20	10 ml

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Επιχειρησιακό πρόγραμμα

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Elettrodo Uretrale Monouso

Destinazione d'uso
Embolizzazione catetere alla rilevazione di segnali biopotenziali mediante l'utilizzo di strumentazione per registrazione, monitoraggio e stimolazione del pavimento pelvico e/o muscolo sfintre uretrale.











Istruzioni per l'uso











- Selezionare la dimensione appropriata del catetere (French (Fr.): 1 French equivale a circa 0,33 mm di diametro del catetere, minore il numero, inferiore è la dimensione del catetere. Calcolare da 8 Fr. a 10 Fr. per adulti e per bambini, da 14 Fr. a 20 Fr. per adulti).
- Prima di iniziare la cateterizzazione, lavare l'area genitale con sapone delicato, acqua tiepida e poi asciugare.
- Verificare lo stato dell'elettrodo uretrale se la confezione è aperta o danneggiata o se il prodotto è scaduto.
- Aprire la busta sterile e rimuovere l'elettrodo uretrale.
- Lubrificare il catetere con un lubrificante a base di acqua, evitando il contatto tra lubrificante e area di stimolazione/registrazione dell'elettrodo.
- Inserire l'elettrodo nell'uretra come un normale catetere non alogar un contatto stabile dell'elettrodo sia con il muscolo sfintre uretrale, sia con il muscolo sfintre esterno.
- Per mantenere la posizione del catetere, gonfiare il palloncino con l'acqua di una siringa senza ago utilizzando una soluzione fisiologica. Seguire la tabella per i valori di gonfiatura:

Fr	Dimensione del palloncino
6	1,5 ml
8	3 ml
10	5 ml
12-20	10 ml











- Creare una leggera trazione verso l'esterno sul catetere per mantenere il posizionamento del palloncino contro lo sfintre uretrale interno.
- Collegare il cavo dell'elettrodo uretrale all'apparecchiatura in uso.
- Una volta terminato l'esame rimuovere completamente la soluzione fisiologica dal palloncino del catetere con l'aiuto di una siringa senza ago. Dopodiché rimuovere l'elettrodo.
- Dopo l'uso gettare l'elettrodo secondo i protocolli standard previsti dall'ospedale per prodotti invasivi.

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





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






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Electrodo uretral desechable

Uso previsto
Embolización catetere destinada a la detección de señales biopotenciales mediante el uso de instrumentación de registro, monitorización y estimulación del suelo pélvico o del músculo del esfínter uretral.

Instrucciones para el uso

- Seleccionar la talla apropiada del tamaño French (Fr.): 1 French equivale a aproximadamente a 0,33 mm de diámetro del catéter. Cuanto menor es el número, más pequeño es el catéter. Los catéteres de 8 Fr. a 10 Fr. son adecuados para niños. Los de 14 Fr. a 20 Fr. para adultos.
- Antes de comenzar la cateterización, limpie el área genital con un jabón suave y agua tibia y luego seque.
- No use el actér de uretra si el paquete está abierto o dañado o si el producto ha caducado.
- Abra el envase estéril y tome el electrodo uretral.
- Verifique la zona de estimulación y de enregistrement sur l'électrode.
- Insérir l'électrode dans l'urètre comme un cathéter normal, afin d'obtenir une interface stable entre la zone d'enregistrement de l'électrode et le muscle sphincter exterieur.
- Para mantener la posición del catéter, inflar el balón con solución fisiológica utilizando una jeringa sin aguja. En la siguiente tabla se muestran los valores de inflado:

Fr	Tamaño de balón
6	1,5 ml
8	3 ml
10	5 ml
12-20	10 ml

- Realizar una suave tracción hacia afuera en el catéter para mantener la posición correcta del balón contra el esfínter uretral interno.
- Conecte el cable del electrodo uretral con el equipo en uso.
- Una vez terminado el examen, retire toda la solución fisiológica del balón del catéter usando una jeringa sin aguja. A continuación, retire el catéter.
- Después del uso, deseché el electrodo de acuerdo con los protocolos estándar del hospital para productos invasivos.

Advertencias

- L'electrodo uretral es un dispositivo desechable. No es stato progettato per il riutilizzo. I tentativi di ripulire o riutilizzare questo dispositivo possono esporre il paziente e gli operatori ad un rischio di contaminazione crociata.
- Durante l'inserimento dell'operatore deve indossare i guanti per proteggersi da infezioni e per prevenire nel paziente.
- Non riutilizzare.
- Non maneggiare con strumenti appuntiti il catetere di supporti all'elettrodo uretrale.
- Il dispositivo deve essere rimosso entro 24 ore al termine dell'intervento, secondo quanto stabilito da un medico o da altro operatore adeguatamente qualificato che abbia dimestichezza con questi dispositivi.
- Gli impulsi elettrici forniti durante la stimolazione devono avere durata dell'ordine di ms e intensità non superiore ai 60-100mA.
- Non maneggiare con strumenti appuntiti il catetere di supporti all'elettrodo uretrale.
- Il dispositivo deve essere rimosso entro 24 ore al fine di la cirugía, según lo determine un médico o otro personal operativamente cualificado que esté familiarizado con estos dispositivos.
- Los impulsos eléctricos suministrados durante la estimulación deben tener una duración de milisegundos de segundos, y una intensidad que no supere los 60-100 mA.
- Durante la lubricación del catéter, evite el contacto entre el lubricante y el área de registro/estimulación del electrodo.
- El personal adidto al utilizarlo es quello medico especializado.
- Si rende necessario il tempo di impiar y realizar este dispositivo desechable puede ser necesario que el usuario o el paciente notifique cualquier incidente grave que se produzca en relación con el dispositivo al fabricante y a la autoridad competente del Estado miembro en el que está establecido el usuario o el paciente.
- Una volta terminato l'esame, rimuovere completamente la soluzione fisiologica dal palloncino del catetere con l'aiuto di una siringa senza ago.
- Dopo l'uso gettare l'elettrodo secondo i protocolli standard previsti dall'ospedale per prodotti invasivi.
- Non ci sono controindicazioni o avvertenze alcuna per donne in gravidanza o allattando.

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