GIMA
PROFESSIONAL MEDICAL PRODUCTS
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MONOFILAMENTO
MONOFILAMENT
MONOFILAMENT
EINZELFADEN
MONOFILAMENTO
MONO-FILAMENTO
MONOMHMATIO
الخيط الوحيد

E' necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.
All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.
Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.
Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.
É necessário notificar ao fabricante e às autoridades competentes do Estado-membro onde ele está sediado qualquer acidente grave verificado em relação ao dispositivo médico fornecido por nós.
Jeder schwere Unfall im Zusammenhang mit dem von uns gelieferten medizinischen Gerät muss unbedingt dem Hersteller und der zuständigen Behörde des Mitgliedsstaats, in dem das Gerät verwendet wird, gemeldet werden.
Σε περίπτωση που διαπιστώσετε οποιοδήποτε σοβαρό περιστατικό σε σχέση με την ιατρική συσκευή που σας παρέχουμε θα πρέπει να το αναφέρετε στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βρίσκεστε.
يجب الإبلاغ عن أي حادث خطير وقع فيما يتعلق بالجهاز الطبي الذي زودنا به إلى الجهة الصانعة والسلطة المختصة في الدولة العضو التي يقع فيها.

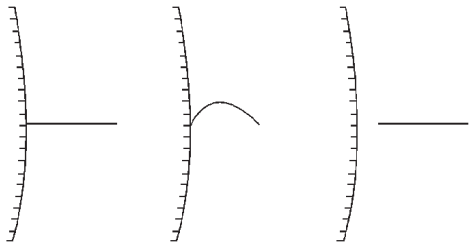
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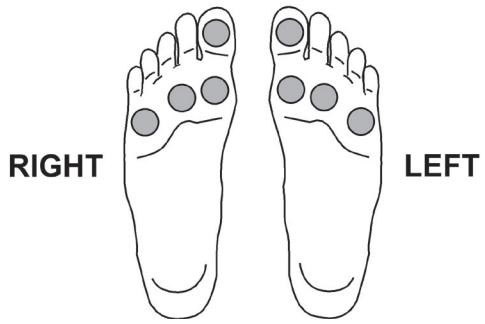
MD

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M31282-M-Rev. 5-12/20



PICTURE 1 PICTURE 2 PICTURE 3



ENGLISH

MONOFILAMENT

Show the filament to the patient and touch it to his/her hand or arm so that he/she knows it does not hurt.

Use the 10 gram filament to test sensation at the indicated sites on each foot as shown. Apply the filament along the perimeter of, and NOT directly on, an ulcer, callus, scar or necrotic tissue.

Hold the filament perpendicular to the skin and use a smoothmotion when testing. Use a 3-step sequence that includes (1) touch the skin, (2) bend the filament, and (3) lift fromthe skin (See Figures 1- 3). Donotuserapidmovement. Theapproach, skincontact, and departure of the filament should be approximately 1.5 seconds in duration.

Ask the patient to respond "yes" when the filament is felt. If the patient does not respond when you touch a given point on the foot, continue on to another site.
When you have completed the sequence, REPEAT on the area(s) where the patient did not indicate feeling the filament.

Use the filament in a random sequence.

LOSS OF PROTECTIVE SENSATION AT ANY ONE OF THE EIGHT SITES (shown on the diagram above) INDICATES A FOOT AT HIGH RISK.

It is recommended to disinfect the product after each use on a patient by using a non-alcoholic antibacterial disinfectant.

REF	GB - Product code FR - Code produit IT - Codice prodotto DE - Erzeugniscode ES - Código producto PT - Código produto GR - Κωδικός προϊόντος SA - كود المنتج	CE	GB Medical Device compliant with Regulation (EU) 2017/745 FR Dispositif médical conforme au règlement (UE) 2017/745 IT Dispositivo medico conforme al regolamento (UE) 2017/745 DE Medizinprodukt im Sinne der Verordnung (EU) 2017/745 ES Producto sanitario conforme con el reglamento (UE) 2017/745 PT Dispositivo médico em conformidade com a regulamento (UE) 2017/745 GR Ιατρική συσκευή σύμφωνα με την ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 SA - جهاز طبي يتوافق مع التوجيه (UE) 2017/745
LOT	GB - Lot number FR - Numéro de lot IT - Numero di lotto DE - Chargennummer ES - Número de lote PT - Número de lote GR - Αριθμός παρτίδας SA - رقم الدفعة		
	GB - Consult instructions for use FR - Consulter les instructions d'utilisation IT - Leggere le istruzioni per l'uso DE - Gebrauchsanweisung beachten ES - Consultar las instrucciones de uso PT - Consulte as instruções de uso GR - Διαβάστε προσεχτικά τις οδηγίες χρήσης SA - اقرأ بدقة وحرص تعليمات الاستخدام		GB - Manufacturer FR - Fabricant IT - Fabbricante DE - Hersteller ES - Fabricante PT - Fabricante GR - Παραγωγός SA - الشركة المصنعة
		MD	GB Medical Device FR Dispositif médical IT Dispositivo medico DE Medizinprodukt ES Producto sanitario PT Dispositivo médico GR Ιατροτεχνολογικό προϊόν SA جهاز طبي