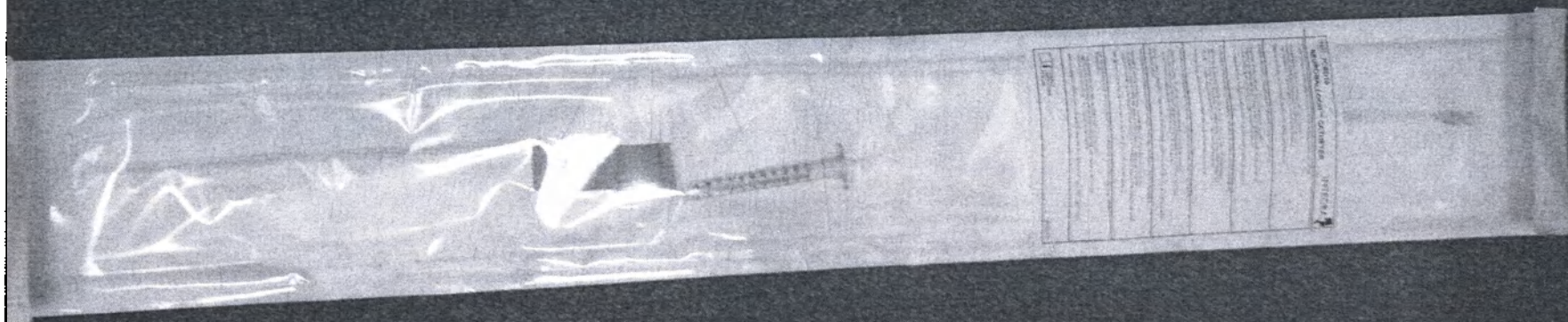


Фотографические изображения медицинского изделия

Катетер NeuroBalloon,

**производства: «Интегра НейроСаенсиз Имплантс (Франция)
С.А.С.» (Integra NeuroSciences Implants (France) S.A.S.),**

2905, Route des Dolines, 06921, Sophia Antipolis Cedex, France





 INTEGRA NEUROBALLOON™ CATHETER 7CBD10	
1. Balloon diameter: 10 mm (3/8 inch) 2. Catheter length: 100 cm (39.4 inches) 3. Catheter outer diameter: 2.5 mm (0.1 inch) 4. Catheter inner diameter: 1.5 mm (0.06 inch) 5. Catheter weight: 100 g (3.5 oz) 6. Catheter material: Polyurethane 7. Catheter color: Blue 8. Catheter markings: 10 cm (4 inches) scale 9. Catheter packaging: Sterile, single use 10. Catheter storage: 2-8°C (36-46°F) 11. Catheter shelf life: 3 years 12. Catheter manufacturer: Integra 13. Catheter model: 7CBD10 14. Catheter lot: 1234567890 15. Catheter expiration: 12/31/2025	
CONTRAINDICATIONS: 1. Known hypersensitivity to polyurethane or any of the components of the catheter. 2. Known or suspected infection at the site of catheter insertion. 3. Known or suspected bleeding disorder or use of anticoagulant therapy. 4. Known or suspected thrombotic disorder or use of thrombolytic therapy. 5. Known or suspected renal or hepatic impairment. 6. Known or suspected cardiac or pulmonary impairment. 7. Known or suspected neurological impairment. 8. Known or suspected spinal cord injury. 9. Known or suspected peripheral vascular disease. 10. Known or suspected aneurysm or other vascular abnormality. 11. Known or suspected tumor or other mass lesion. 12. Known or suspected infection of the central nervous system. 13. Known or suspected infection of the respiratory system. 14. Known or suspected infection of the urinary system. 15. Known or suspected infection of the gastrointestinal system.	
WARNINGS: 1. Do not use if the catheter is damaged or if the balloon is torn. 2. Do not use if the catheter is contaminated. 3. Do not use if the catheter is expired. 4. Do not use if the catheter is not sterile. 5. Do not use if the catheter is not intended for single use. 6. Do not use if the catheter is not intended for intracranial use. 7. Do not use if the catheter is not intended for intrathecal use. 8. Do not use if the catheter is not intended for intraventricular use. 9. Do not use if the catheter is not intended for intracystic use. 10. Do not use if the catheter is not intended for intraneural use. 11. Do not use if the catheter is not intended for intraspinal use. 12. Do not use if the catheter is not intended for intracranial, intrathecal, intraventricular, intracystic, intraneural, or intraspinal use.	
INSTRUCTIONS FOR USE: 1. Remove the catheter from its sterile packaging. 2. Inspect the catheter for damage or defects. 3. Prepare the catheter for use according to the instructions for use. 4. Insert the catheter into the patient's body. 5. Advance the catheter until the balloon is in the desired position. 6. Inflate the balloon with the appropriate volume of contrast medium. 7. Observe the catheter and balloon under fluoroscopic guidance. 8. Deflate the balloon and withdraw the catheter. 9. Dispose of the catheter appropriately. 10. Do not reuse the catheter.	
STERILIZATION: 1. The catheter is sterilized by gamma irradiation. 2. The catheter is packaged in a sterile, leak-proof container. 3. The catheter is stored in a cool, dry place. 4. The catheter is used within the expiration date.	
LOT NUMBER: 1234567890 EXP. DATE: 12/31/2025 MANUFACTURED BY: INTEGRA MADE IN: USA	

NEUROBALLOON™ CATHETER

INTEGRA

REF 7CBD10

LOT 0206412

2018-01-22

2020-01-22

NEUROBALLOON™ CATHETER - For dilation of cerebral aneurysms. For dilation of a minimum diameter (1.35 mm). Balloon used diameter upon inflation: 3.5 mm minimum at 0.6 m (0.6 cc) of air, 6 mm maximum at 1 m (1 cc) of air.

NEUROBALLOON™ CATHETER - Pour la dilation d'une aneurysme d'un diamètre minimum. Pour la dilation d'un diamètre minimum (1.35 mm). Diamètre d'élargissement du ballonnet au gonflement: 3.5 mm minimum pour 0.6 m (0.6 cc) d'air, 6 mm maximum pour 1 m (1 cc) d'air.

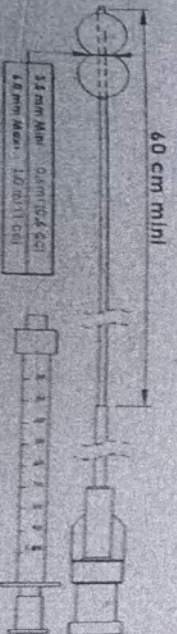
NEUROBALLOON™ CATHETER - Zur Dilation eines aneurysm. Mindestaufblähschritt: 3.5 mm bei 0.6 m (0.6 cc) Luft und maximal 6 mm bei 1 m (1 cc) Luft.

NEUROBALLOON™ CATHETER - Para a dilatação de uma aneurisma cerebral. Para introdução em um diâmetro mínimo de 1.35 mm. Diâmetro de restrição do balão depois de inflado: mínimo de 3.5 mm com 0.6 ml (0.6 cc) de volume de ar, máximo de 6 mm com 1 ml (1 cc) de volume de ar.

NEUROBALLOON™ CATHETER - Para a dilatación de aneurismas practicados en la neurocirugía cerebral. Para insertar en un diámetro mínimo (1.35 mm). Diámetro de la red de balón después de inflado: mínimo de 3.5 mm con 0.6 ml (0.6 cc) de volumen de aire, máximo de 6 mm con 1 ml (1 cc) de volumen de aire.

NEUROBALLOON™ CATHETER - Voor dilatie van openingen in het hersenventriaal Vlier. Invoeren in een af minimaal diameter (1.35 mm). Diameter balon na inflatie: 3.5 mm minimaal bij 0.6 m (0.6 cc) lucht, 6 mm maximaal bij 1 m (1 cc) lucht.

RX ONLY



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NEUROBALLOON™ CATHETER

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2020-01-22

2020-01-22

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Tel: 978.686.1000
Fax: 978.686.1001

CE 0086

B131025-02

NEUROBALLOON™ CATHETER - For dilatation of cerebral membrane fenestrations. For insertion into a F4 minimum diameter (1,35 mm). Balloon waist diameter upon inflation: 3,5 mm minimum at 0,6ml (0,6cc) of air, 6 mm maximum at 1 ml (1cc) of air.

NEUROBALLOON™ CATHETER - Pour la dilatation d'une ouverture dans une membrane cérébrale. Pour introduction dans un diamètre minimum F4 (1,35 mm). Diamètre d'étranglement du ballonnet au gonflage: 3,5 mm minimum pour 0,6ml (0,6cc) d'air, 6 mm maximum pour 1 ml (1cc) d'air.

NEUROBALLOON™ CATHETER - Zur Dilatation zerebraler Membranfensterungen. Zur Einführung in Mindestdurchmesser F4 (1,35 mm). Der Durchmesser der inflatierten Ballontaille beträgt mindestens 3,5 mm bei 0,6 ml (0,6cc) Luft und maximal 6 mm bei 1 ml (1cc) Luft.

NEUROBALLOON™ CATHETER - Per la dilatazione di fenestrazioni della membrana cerebrale. Per l'introduzione in un diametro minimo di 4F (1,35 mm). Diametro del restringimento del palloncino gonfiato: minimo 3,5 mm con 0,6 ml (0,6cc) d'aria, massimo: 6 mm con 1 ml (1cc) d'aria.

NEUROBALLOON™ CATHETER - Para la dilatación de aberturas practicadas en la membrana cerebral. Para insertar en un diámetro mínimo F4 (1,35 mm). Diámetro de la cintura del balón después del inflado: mínimo de 3,5 mm con 0,6ml (0,6cc) de volumen de aire, máximo de 6 mm con 1 ml (1cc) de volumen de aire.

NEUROBALLOON™ CATHETER - Voor dilatatie van openingen in het hersenmembraan. Voor insertie in een 4F minimale diameter (1,35 mm). Diameter ballontaille bij inflatie: 3,5 mm minimaal bij 0,6 ml (0,6 cc) lucht, 6 mm maximaal bij 1 ml (1 cc) lucht.

 **CONSULT INSTRUCTIONS FOR USE**

STERILE EO

STERILIZED USING ETHYLENE OXIDE



DO NOT RE-USE



LATEX



DO NOT USE IF PACKAGE IS DAMAGED

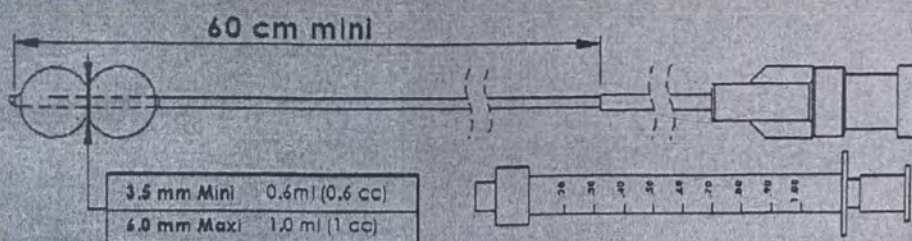


DO NOT RESTERILIZE



NON PYROGENIC

Rx ONLY



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NEUROBALLOON™ CATHETER



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CE
0086

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и скреплено печатью

6 (шесть) лист об

Директор Ч Чебурашкин Д.М.

