Rocketmedical

CUSTOMER INFORMATION BULLETIN

Perinatal Care

Rocket® KCH™ Catheters & MRI

Indications for Use: The Rocket KCH™ Fetal Bladder Drainage Catheter (R57405) is intended for use in fetal bladder decompression following diagnosis of fetal post-vesicular obstructive uropathy in foetuses of 18-22 weeks gestation.

The device is for use by or under the direct supervision of trained personnel and accordance with national guidelines such as: *Interventional procedure guidance 190: Insertion of pleuro–amniotic shunt for fetal pleural effusion.* NICE Sept 2006 *and Interventional procedure guidance 202: Fetal vesico–amniotic shunt for lower urinary tract outflow obstruction.* NICE Dec. 2006.

Humanitarian Device: Authorised by Federal law for use in the treatment of Fetal obstructive uropathy. The effectiveness of this device has not been demonstrated

Device Description: The device is a double pigtail stent with an outer tube diameter of 2.1mm and inner tube diameter of 1.5mm. The coils are wound to 18mm diameters, 30mm between the coils. The proximal pigtail being a double coil orientated perpendicular to the stent to allow the pigtail to lie flat against the Fetal abdomen. The distal pigtail is a one and a half coil orientated horizontally to the stent in order to hold the pigtail inside the Fetal bladder. Both coils have 3 side ports, with distal coil markers for ultrasound visualisation.

Materials: Austenitic (non-magnetic) Stainless 316-316L Steel rings are inserted under pressure within each distal lumen of the tube material.

Marker Ring Dimensions:

- O.D 1.65mm (1.6mm to 1.7mm)
- Length 2mm (1.7mm to 2.3mm).
- ID 1.2mm nominal

Usage with Magnetic Resonance Imaging (MRI): Rocket Medical plc. can confirm, that anecdotally, we are aware that the Rocket® KCH™ Catheter has been successfully used in conjunction with MRI. Since 2003, over 4,200 Rocket® KCH™ catheters have been inserted and it is believed that the majority of these have been subject to MRI screening.

Although Rocket Medical plc. does not have access to the specific details of the conditions under which those scans were completed, we are not aware of any reports either received directly by the company or made to the UK Regulatory bodies (MHRA) or FDA of any adverse incident involving this device and MRI.

The minimal mass of the austenitic marker rings is understood to be insufficient to create migration of the catheter under normal screening conditions. However a specific maximum MR-Conditional field density or strength cannot be validated or therefore recommended.

The decision to use MRI screening must be taken in conjunction with qualified Radiological guidance and only on the basis of the clinical benefit versus the potential risk of screening.

Customer Information Bulletins on all of our products can be found on our web site at: www.rocketmedical.com

If you have any questions, please contact the Customer Services Team for assistance:
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