



**Clinical trial results:**  
**UK Multicentre Open-label Randomised Controlled Trial Of IV Iron Therapy**  
**In Incident Haemodialysis Patients**  
**Summary**

EudraCT number	2013-002267-25
Trial protocol	GB
Global end of trial date	06 June 2018

**Results information**

Result version number	v1 (current)
This version publication date	04 August 2019
First version publication date	04 August 2019
Summary attachment (see zip file)	Final Publication (NEJMoa1810742.pdf)

**Trial information****Trial identification**

Sponsor protocol code	PIVOTAL
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

Sponsor organisation name	King's College Hospital NHS Foundation Trust
Sponsor organisation address	Denmark Hill, London, United Kingdom, SE5 9RS
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Notes:

**Paediatric regulatory details**

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 June 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 June 2018
Global end of trial reached?	Yes
Global end of trial date	06 June 2018
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To compare the effect of a proactive high-dose, with a reactive low-dose, IV iron regimen on all-cause mortality and the incidence of non-fatal cardiovascular endpoints in haemodialysis patients.

Protection of trial subjects:

During the period between informed consent and randomisation, if there is a strong clinical indication that a patient requires iron, then iron may be administered (this is not considered to be a protocol breach).

Background therapy:

Patients established on a chronic haemodialysis programme for end-stage renal failure

Evidence for comparator:

To compare the effect of a proactive high-dose, with a reactive low-dose, IV iron regimen on all-cause mortality and the incidence of non-fatal cardiovascular endpoints in haemodialysis patients

Actual start date of recruitment	01 September 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 2141
Worldwide total number of subjects	2141
EEA total number of subjects	2141

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	865
From 65 to 84 years	1024



## Subject disposition

### Recruitment

Recruitment details:

Participants were recruited from multiple clinical centres across the UK between 2013 and 2018

### Pre-assignment

Screening details:

Age >18 years

- Patients established on a chronic haemodialysis programme for end-stage renal failure
- Clinically stable (Investigator's judgement)
- 0–12 months since commencing haemodialysis

### Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:  
not applicable

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Proactive IV iron arm

Arm description:

IV iron 400mg/month

Total study period approximately 4 years (event-driven)

– projected treatment duration per patient > 2 years

Arm type	Experimental
Investigational medicinal product name	Venofer
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

IV iron 400mg/month by Intravenous Infusion

<b>Arm title</b>	Reactive IV iron arm
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Arm description:

IV iron sucrose 100–200mg / month if becomes "iron deficien

Arm type	Active comparator
Investigational medicinal product name	Venofer
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

IV iron sucrose 100–200mg / month if becomes "iron deficien

<b>Number of subjects in period 1</b>	Proactive IV iron arm	Reactive IV iron arm
Started	1093	1048
Completed	488	407
Not completed	605	641
Adverse event, serious fatal	246	269
Consent withdrawn by subject	42	44
Moved to peritoneal dialysis	13	17
Home dialysis	45	36
Lost to follow-up	62	78
Transplant	184	187
Protocol deviation	13	10

## Baseline characteristics

## End points

### End points reporting groups

Reporting group title	Proactive IV iron arm
Reporting group description: IV iron 400mg/month Total study period approximately 4 years (event-driven) - projected treatment duration per patient > 2 years	
Reporting group title	Reactive IV iron arm
Reporting group description: IV iron sucrose 100–200mg / month if becomes "iron deficient"	

### Primary: Time to first event

End point title	Time to first event <sup>[1]</sup>
End point description: Time to first event: all-cause death or a composite of non-fatal cardiovascular events (myocardial infarction, stroke, and hospitalisation for heart failure) adjudicated by a blinded Endpoint Adjudication Committee.	
End point type	Primary
End point timeframe: not applicable	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Please see attached publication and appendix	

End point values	Proactive IV iron arm	Reactive IV iron arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1080	1038		
Units: whole	1080	1038		

<b>Attachments (see zip file)</b>	Results additional data/nejmoa1810742_appendix.pdf
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### Statistical analyses

No statistical analyses for this end point

### Secondary: Secondary Efficacy Endpoints

End point title	Secondary Efficacy Endpoints
End point description: Incidence of all-cause death and a composite of myocardial infarction, stroke, and hospitalisation for heart failure as recurrent events. - Time to (and incidence of) all-cause death - Time to (and incidence of) first composite cardiovascular event - Time to (and incidence of) first myocardial infarction - Time to (and incidence of) first stroke - Time to (and incidence of) first hospitalisation for heart failure - Transfusion requirements	

- EQ-5D QOL and KDQOL
- ESA dose requirements

End point type	Secondary
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End point timeframe:	
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0 to 18 months (event driven)	
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<b>End point values</b>	Proactive IV iron arm	Reactive IV iron arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1080	1038		
Units: whole	1080	1038		

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

Adverse events were recorded from baseline/randomisation until the end of study for each patient.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

### Reporting groups

Reporting group title	Proactive IV Iron
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Reporting group description: -

Reporting group title	Reactive IV Iron
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Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Adverse events or reactions listed in the SmPC were not reported, with the exception of immediate hypersensitivity-like reactions to IV iron. Common non-life-threatening symptoms such as constipation, diarrhoea, headache, etc. do not need to be reported. Only serious adverse events and episodes of infection and vascular access thrombosis will be recorded. No other non-serious adverse events will be recorded.

Serious adverse events	Proactive IV Iron	Reactive IV Iron	
Total subjects affected by serious adverse events			
subjects affected / exposed	709 / 1093 (64.87%)	671 / 1048 (64.03%)	
number of deaths (all causes)	246	269	
number of deaths resulting from adverse events	246	269	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADRENAL NEOPLASM			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER CANCER			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
BLADDER NEOPLASM			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>BLADDER TRANSITIONAL CELL CARCINOMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BREAST CANCER</b>		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>CARDIAC MYXOMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CENTRAL NERVOUS SYSTEM LYMPHOMA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CERVIX CANCER METASTATIC</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>COLON CANCER</b>		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>GASTRIC CANCER</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GASTROINTESTINAL CARCINOMA</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HEPATIC NEOPLASM MALIGNANT</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LUNG ADENOCARCINOMA</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LUNG CANCER METASTATIC</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>LUNG NEOPLASM MALIGNANT</b>		
subjects affected / exposed	4 / 1093 (0.37%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2
<b>LUNG SQUAMOUS CELL CARCINOMA STAGE UNSPECIFIED</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LYMPHOMA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>MALIGNANT MELANOMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MEDIASTINUM NEOPLASM</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>MESOTHELIOMA MALIGNANT</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>METASTASES TO CENTRAL NERVOUS SYSTEM</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>METASTASES TO PANCREAS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>METASTASIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>METASTATIC MALIGNANT MELANOMA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>METASTATIC NEOPLASM</b>		
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
<b>MULTIPLE MYELOMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>NEOPLASM MALIGNANT</b>		

subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>NEUROENDOCRINE TUMOUR</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NON-SMALL CELL LUNG CANCER</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PANCREATIC CARCINOMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>PELVIC NEOPLASM</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PITUITARY TUMOUR BENIGN</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PLEURAL NEOPLASM</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>PROSTATE CANCER METASTATIC</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RECTAL CANCER</b>		

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>RENAL CANCER RECURRENT</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>RENAL CELL CARCINOMA RECURRENT</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SALIVARY GLAND CANCER</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SKIN CANCER</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SMALL CELL LUNG CANCER STAGE UNSPECIFIED</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>VULVAL CANCER</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>PROGRESSIVE SUPRANUCLEAR PALSY</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular disorders</b>			

Stroke			
subjects affected / exposed	12 / 1093 (1.10%)	13 / 1048 (1.24%)	
occurrences causally related to treatment / all	0 / 12	0 / 13	
deaths causally related to treatment / all	0 / 12	0 / 13	
AIR EMBOLISM			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANEURYSM RUPTURED			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
ANGIOPATHY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
AORTIC ANEURYSM			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
AORTIC CALCIFICATION			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
AORTIC STENOSIS			
subjects affected / exposed	0 / 1093 (0.00%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
ARTERIAL DISORDER			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOSCLEROSIS			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ARTERIOVENOUS FISTULA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BRACHIOCEPHALIC ARTERY OCCLUSION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CIRCULATORY COLLAPSE</b>		
subjects affected / exposed	17 / 1093 (1.56%)	16 / 1048 (1.53%)
occurrences causally related to treatment / all	0 / 22	0 / 18
deaths causally related to treatment / all	0 / 5	0 / 4
<b>DEEP VEIN THROMBOSIS</b>		
subjects affected / exposed	3 / 1093 (0.27%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
<b>DIABETIC VASCULAR DISORDER</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>EMBOLISM</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>VENOUS EMBOLISM</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>EXTREMITY NECROSIS</b>		

subjects affected / exposed	5 / 1093 (0.46%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
<b>HAEMATOMA</b>		
subjects affected / exposed	6 / 1093 (0.55%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HAEMORRHAGE</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HYPERTENSION</b>		
subjects affected / exposed	10 / 1093 (0.91%)	6 / 1048 (0.57%)
occurrences causally related to treatment / all	0 / 12	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
<b>HYPERTENSIVE CRISIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HYPOTENSION</b>		
subjects affected / exposed	20 / 1093 (1.83%)	18 / 1048 (1.72%)
occurrences causally related to treatment / all	0 / 22	0 / 20
deaths causally related to treatment / all	0 / 2	0 / 3
<b>HYPOVOLAEMIC SHOCK</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>INTERMITTENT CLAUDICATION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MALIGNANT HYPERTENSION</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MICROSCOPIC POLYANGIITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ORTHOSTATIC HYPOTENSION</b>		
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERIPHERAL ARTERIAL OCCLUSIVE DISEASE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERIPHERAL ARTERY THROMBOSIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERIPHERAL ISCHAEMIA</b>		
subjects affected / exposed	14 / 1093 (1.28%)	22 / 1048 (2.10%)
occurrences causally related to treatment / all	0 / 15	0 / 25
deaths causally related to treatment / all	0 / 4	0 / 7
<b>PERIPHERAL VASCULAR DISORDER</b>		
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
<b>STEAL SYNDROME</b>		
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SUPERIOR VENA CAVA SYNDROME</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>THROMBOSIS</b>			
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>VASCULAR STENOSIS</b>			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>VENOUS OCCLUSION</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>VENOUS STENOSIS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>VENA CAVA THROMBOSIS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>TEMPORAL ARTERITIS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>POOR VENOUS ACCESS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Surgical and medical procedures</b>			
<b>ABSCISS DRAINAGE</b>			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>AMPUTATION OF PENIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>ANEURYSM REPAIR</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ANGIOPLASTY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ANKLE OPERATION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>AORTIC VALVE REPLACEMENT</b>		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ARTERIOVENOUS FISTULA OPERATION</b>		
subjects affected / exposed	29 / 1093 (2.65%)	18 / 1048 (1.72%)
occurrences causally related to treatment / all	0 / 34	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ARTERIOVENOUS GRAFT</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BLADDER NECK OPERATION</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BUNION OPERATION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CARDIAC PACEMAKER INSERTION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CARPAL TUNNEL DECOMPRESSION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CATHETER PLACEMENT</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CATHETER REMOVAL</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CENTRAL VENOUS CATHETERISATION</b>		
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CHOLECYSTECTOMY</b>		
subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CORONARY ANGIOPLASTY</b>		

subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CORONARY ARTERIAL STENT INSERTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CORONARY ARTERY BYPASS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DEBRIDEMENT</b>		
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DIALYSIS</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DIALYSIS DEVICE INSERTION</b>		
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DRUG THERAPY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>EMERGENCY CARE</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>EMPYEMA DRAINAGE</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>ENDOTRACHEAL INTUBATION</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>FINGER AMPUTATION</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>FISTULA REPAIR</b>			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>FOOT AMPUTATION</b>			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>GASTROINTESTINAL SURGERY</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>GENITOURINARY OPERATION</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>HERNIA REPAIR</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>HIP ARTHROPLASTY</b>			

subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>HOSPITALISATION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HYSTERECTOMY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ILEOSTOMY</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INCISIONAL DRAINAGE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INCISIONAL HERNIA REPAIR</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>INTRAVENOUS CATHETER MANAGEMENT</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>KNEE ARTHROPLASTY</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LEG AMPUTATION</b>		

subjects affected / exposed	7 / 1093 (0.64%)	7 / 1048 (0.67%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LESION EXCISION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LIMB AMPUTATION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MALIGNANT TUMOUR EXCISION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MASTECTOMY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MENISCUS OPERATION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NEPHRECTOMY</b>		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
<b>OPEN REDUCTION OF FRACTURE</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>OVARIOCENTESIS</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PANCREATODUODENECTOMY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PARATHYROIDECTOMY</b>		
subjects affected / exposed	9 / 1093 (0.82%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PARTIAL LUNG RESECTION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERCUTANEOUS CORONARY INTERVENTION</b>		
subjects affected / exposed	5 / 1093 (0.46%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERIPHERAL ARTERY ANGIOPLASTY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERIPHERAL ARTERY BYPASS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PREOPERATIVE CARE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PROLAPSE REPAIR</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
PROPHYLAXIS		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
RENAL TRANSPLANT		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SALPINGO-OOPHORECTOMY UNILATERAL		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SALVAGE THERAPY		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SKIN GRAFT		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SKIN NEOPLASM EXCISION		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SURGERY		
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
THERAPY CESSATION		

subjects affected / exposed	7 / 1093 (0.64%)	8 / 1048 (0.76%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 7	0 / 8
THORACIC CAVITY DRAINAGE		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
THROMBECTOMY		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
THROMBOEMBOLECTOMY		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
THROMBOLYSIS		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
THROMBOSIS PROPHYLAXIS		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
TOE AMPUTATION		
subjects affected / exposed	6 / 1093 (0.55%)	7 / 1048 (0.67%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
TRANSFUSION		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
URETERAL STENT INSERTION		

subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>URINARY TRACT OPERATION</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>UROSTOMY</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>VASCULAR OPERATION</b>			
subjects affected / exposed	15 / 1093 (1.37%)	8 / 1048 (0.76%)	
occurrences causally related to treatment / all	0 / 15	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>General disorders and administration site conditions</b>			
<b>Adverse drug reaction</b>			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Asthenia</b>			
subjects affected / exposed	6 / 1093 (0.55%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
<b>Cardiac death</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Catheter site haemorrhage</b>			
subjects affected / exposed	1 / 1093 (0.09%)	12 / 1048 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Catheter site pain</b>			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest discomfort		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	52 / 1093 (4.76%)	51 / 1048 (4.87%)
occurrences causally related to treatment / all	0 / 72	0 / 67
deaths causally related to treatment / all	0 / 3	0 / 2
Chills		
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Complication of device removal		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	34 / 1093 (3.11%)	28 / 1048 (2.67%)
occurrences causally related to treatment / all	0 / 34	0 / 28
deaths causally related to treatment / all	0 / 34	0 / 28
Device dislocation		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device occlusion		
subjects affected / exposed	7 / 1093 (0.64%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Drug resistance		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue management		
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	5 / 1093 (0.46%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 2
Hernia		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypothermia		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Injury associated with device		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ischaemic ulcer		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
local swelling		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malaise</b>		
subjects affected / exposed	18 / 1093 (1.65%)	10 / 1048 (0.95%)
occurrences causally related to treatment / all	0 / 19	0 / 12
deaths causally related to treatment / all	0 / 3	0 / 1
<b>medical device complication</b>		
subjects affected / exposed	10 / 1093 (0.91%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multi-organ failure</b>		
subjects affected / exposed	5 / 1093 (0.46%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 5	0 / 1
<b>Necrosis</b>		
subjects affected / exposed	6 / 1093 (0.55%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-cardiac chest pain</b>		
subjects affected / exposed	0 / 1093 (0.00%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oedema peripheral</b>		
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pain</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic mass</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pyrexia</b>			
subjects affected / exposed	17 / 1093 (1.56%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 18	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Sudden cardiac death</b>			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
<b>Sudden unexplained death in epilepsy</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Swelling</b>			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Suprapubic pain</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Treatment failure</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Immune system disorders</b>			
<b>DRUG HYPERSENSITIVITY</b>			
subjects affected / exposed	13 / 1093 (1.19%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>HEART TRANSPLANT REJECTION</b>			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>CONTRAST MEDIA ALLERGY</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Social circumstances</b>			
<b>SOCIAL PROBLEM</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SOCIAL STAY HOSPITALISATION</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>TREATMENT NONCOMPLIANCE</b>			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
<b>EPIDIDYMITIS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>FEMALE GENITAL TRACT FISTULA</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>PELVIC HAEMATOMA</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

<b>PENILE NECROSIS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>VAGINAL HAEMORRHAGE</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>PLEURAL EFFUSION</b>			
subjects affected / exposed	22 / 1093 (2.01%)	19 / 1048 (1.81%)	
occurrences causally related to treatment / all	0 / 25	0 / 27	
deaths causally related to treatment / all	0 / 2	0 / 4	
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>ACUTE PULMONARY OEDEMA</b>			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
<b>ACUTE RESPIRATORY FAILURE</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ALVEOLITIS ALLERGIC</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ASPIRATION</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>ASTHMA</b>			
subjects affected / exposed	1 / 1093 (0.09%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	

<b>BRONCHIECTASIS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>CHOKING</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>CHRONIC OBSTRUCTIVE PULMONARY DISEASE</b>			
subjects affected / exposed	8 / 1093 (0.73%)	14 / 1048 (1.34%)	
occurrences causally related to treatment / all	0 / 10	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 3	
<b>CHRONIC RESPIRATORY FAILURE</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>COUGH</b>			
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>DYSPNOEA</b>			
subjects affected / exposed	42 / 1093 (3.84%)	43 / 1048 (4.10%)	
occurrences causally related to treatment / all	0 / 53	0 / 50	
deaths causally related to treatment / all	0 / 2	0 / 6	
<b>EMPHYSEMA</b>			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>EPISTAXIS</b>			
subjects affected / exposed	5 / 1093 (0.46%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>HAEMOPTYSIS</b>			

subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HAEMOTHORAX</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
<b>LARYNGEAL DYSPNOEA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>LARYNGEAL STENOSIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NON-CARDIOGENIC PULMONARY OEDEMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LUNG DISORDER</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LUNG CONSOLIDATION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HYPOXIA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>DYSPNOEA EXERTIONAL</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PLEURISY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PLEURITIC PAIN</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PNEUMONIA ASPIRATION</b>		
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
<b>PNEUMOTHORAX</b>		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>PRODUCTIVE COUGH</b>		
subjects affected / exposed	3 / 1093 (0.27%)	7 / 1048 (0.67%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PULMONARY ARTERY ANEURYSM</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PULMONARY CONGESTION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PULMONARY EMBOLISM</b>		

subjects affected / exposed	6 / 1093 (0.55%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
<b>PULMONARY FIBROSIS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>PULMONARY OEDEMA</b>			
subjects affected / exposed	25 / 1093 (2.29%)	27 / 1048 (2.58%)	
occurrences causally related to treatment / all	0 / 25	0 / 35	
deaths causally related to treatment / all	0 / 1	0 / 3	
<b>RESPIRATORY ARREST</b>			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>RESPIRATORY DISORDER</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>RESPIRATORY DISTRESS</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>RESPIRATORY FAILURE</b>			
subjects affected / exposed	2 / 1093 (0.18%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 2	
<b>WHEEZING</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Psychiatric disorders			
AFFECT LABILITY			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>AGITATION</b>			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ANXIETY</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>CONFUSIONAL STATE</b>			
subjects affected / exposed	18 / 1093 (1.65%)	18 / 1048 (1.72%)	
occurrences causally related to treatment / all	0 / 23	0 / 19	
deaths causally related to treatment / all	0 / 3	0 / 4	
<b>DELIRIUM</b>			
subjects affected / exposed	3 / 1093 (0.27%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>DEPRESSED MOOD</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>IMPAIRED SELF-CARE</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>PSYCHOTIC DISORDER</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatobiliary disorders</b>			
Bile duct obstruction			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bile duct stenosis</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Biliary colic</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholangitis</b>		
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholecystitis</b>		
subjects affected / exposed	8 / 1093 (0.73%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholecystitis acute</b>		
subjects affected / exposed	3 / 1093 (0.27%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholelithiasis</b>		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gallbladder perforation</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic cirrhosis</b>		

subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Hepatitis acute</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Hepatic failure</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Jaundice</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Jaundice cholestatic</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Liver disorder</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Investigations</b>			
<b>ANTICOAGULATION DRUG LEVEL ABOVE THERAPEUTIC</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>CORONARY ARTERIOGRAM</b>			
subjects affected / exposed	0 / 1093 (0.00%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>BIOPSY LYMPH GLAND</b>			

subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BLOOD CULTURE POSITIVE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BLOOD GLUCOSE ABNORMAL</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BLOOD GLUCOSE FLUCTUATION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BLOOD GLUCOSE INCREASED</b>		
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BLOOD PHOSPHORUS DECREASED</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BLOOD POTASSIUM INCREASED</b>		
subjects affected / exposed	4 / 1093 (0.37%)	6 / 1048 (0.57%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BLOOD PRESSURE INCREASED</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CARDIAC OUTPUT DECREASED</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
CARDIAC PACEMAKER EVALUATION		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
CLOSTRIDIUM TEST POSITIVE		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
COLONOSCOPY		
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
COMA SCALE ABNORMAL		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
C-REACTIVE PROTEIN ABNORMAL		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
C-REACTIVE PROTEIN INCREASED		
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
DRUG LEVEL ABOVE THERAPEUTIC		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
ECHOCARDIOGRAM ABNORMAL		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ELECTROCARDIOGRAM ABNORMAL</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>FISTULOGRAM</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DECREASED HAEMOGLOBIN</b>		
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HEART RATE IRREGULAR</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INFLAMMATORY MARKER INCREASED</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INTERNATIONAL NORMALISED RATIO ABNORMAL</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INTERNATIONAL NORMALISED</b>		

RATIO INCREASED			
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
LISTERIA TEST POSITIVE			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDIASTINOSCOPY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY FUNCTION TEST DECREASED			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SIGMOIDOSCOPY			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TROPONIN INCREASED			
subjects affected / exposed	1 / 1093 (0.09%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCREASED T TROPONIN			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINE OUTPUT DECREASED			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>WEIGHT DECREASED</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Injury, poisoning and procedural complications</b>			
<b>ACCIDENTAL OVERDOSE</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ANKLE FRACTURE</b>			
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ANEURYSM ARTERIOVENOUS FISTULA</b>			
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ARTERIOVENOUS FISTULA OCCLUSION</b>			
subjects affected / exposed	34 / 1093 (3.11%)	33 / 1048 (3.15%)	
occurrences causally related to treatment / all	0 / 38	0 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ACCIDENT</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>ARTERIOVENOUS FISTULA SITE COMPLICATION</b>			
subjects affected / exposed	24 / 1093 (2.20%)	20 / 1048 (1.91%)	
occurrences causally related to treatment / all	0 / 24	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 1	

ARTERIOVENOUS FISTULA SITE HAEMORRHAGE		
subjects affected / exposed	12 / 1093 (1.10%)	12 / 1048 (1.15%)
occurrences causally related to treatment / all	0 / 13	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
ARTERIOVENOUS FISTULA THROMBOSIS		
subjects affected / exposed	43 / 1093 (3.93%)	27 / 1048 (2.58%)
occurrences causally related to treatment / all	0 / 52	0 / 28
deaths causally related to treatment / all	0 / 1	0 / 0
ARTERIOVENOUS GRAFT SITE HAEMATOMA		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
CERVICAL VERTEBRAL FRACTURE		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
CLAVICLE FRACTURE		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
COMPLICATIONS OF TRANSPLANT SURGERY		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
CONTUSION		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
DIALYSIS RELATED COMPLICATION		
subjects affected / exposed	7 / 1093 (0.64%)	7 / 1048 (0.67%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 2

FACE INJURY			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FALL			
subjects affected / exposed	33 / 1093 (3.02%)	55 / 1048 (5.25%)	
occurrences causally related to treatment / all	0 / 39	0 / 59	
deaths causally related to treatment / all	0 / 1	0 / 13	
FEMORAL NECK FRACTURE			
subjects affected / exposed	13 / 1093 (1.19%)	23 / 1048 (2.19%)	
occurrences causally related to treatment / all	0 / 14	0 / 24	
deaths causally related to treatment / all	0 / 2	0 / 2	
FEMUR FRACTURE			
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
FIBULA FRACTURE			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOOT FRACTURE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
FOREIGN BODY			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FRACTURE			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
GASTROINTESTINAL STOMA COMPLICATION			

subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GRAFT COMPLICATION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GRAFT HAEMORRHAGE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GRAFT THROMBOSIS</b>		
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HAEMATURIA TRAUMATIC</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HAEMODIALYSIS COMPLICATION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
<b>HAEMODIALYSIS-INDUCED SYMPTOM</b>		
subjects affected / exposed	4 / 1093 (0.37%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HAND FRACTURE</b>		
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HEAD INJURY</b>		

subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HEPATIC HAEMATOMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HIP FRACTURE</b>		
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
<b>HUMERUS FRACTURE</b>		
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>IATROGENIC INJURY</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INCISIONAL HERNIA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INCISIONAL HERNIA, OBSTRUCTIVE</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INJURY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>JOINT DISLOCATION</b>		

subjects affected / exposed	0 / 1093 (0.00%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>JOINT INJURY</b>		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LACERATION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LIMB INJURY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LOWER LIMB FRACTURE</b>		
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MULTIPLE FRACTURES</b>		
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MUSCLE INJURY</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>OVERDOSE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PATELLA FRACTURE</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PELVIC FRACTURE</b>		
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERIPROSTHETIC FRACTURE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERITONEAL DIALYSIS COMPLICATION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POST GASTRIC SURGERY SYNDROME</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POST PROCEDURAL COMPLICATION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POST PROCEDURAL DIARRHOEA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POST PROCEDURAL HAEMATOMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POST PROCEDURAL MYOCARDIAL INFARCTION</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>POST PROCEDURAL SWELLING</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POSTOPERATIVE ILEUS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>POSTOPERATIVE WOUND COMPLICATION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PROCEDURAL COMPLICATION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PROCEDURAL HAEMORRHAGE</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PROCEDURAL HYPERTENSION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PROCEDURAL HYPOTENSION</b>		
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1
<b>PROCEDURAL PAIN</b>		

subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PROCEDURAL VOMITING</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PUBIS FRACTURE</b>		
subjects affected / exposed	2 / 1093 (0.18%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RADIUS FRACTURE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RENAL GRAFT LOSS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RIB FRACTURE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ROAD TRAFFIC ACCIDENT</b>		
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>SHUNT OCCLUSION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SOFT TISSUE INJURY</b>		

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SPINAL FRACTURE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>SUBDURAL HAEMATOMA</b>		
subjects affected / exposed	4 / 1093 (0.37%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>SUBDURAL HAEMORRHAGE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>TIBIA FRACTURE</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>TOXICITY TO VARIOUS AGENTS</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>TRAUMATIC HAEMATOMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>UPPER LIMB FRACTURE</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>VASCULAR ACCESS COMPLICATION</b>		

subjects affected / exposed	20 / 1093 (1.83%)	13 / 1048 (1.24%)
occurrences causally related to treatment / all	0 / 24	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 1
<b>VASCULAR GRAFT COMPLICATION</b>		
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>VASCULAR GRAFT OCCLUSION</b>		
subjects affected / exposed	8 / 1093 (0.73%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 11	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>VASCULAR GRAFT THROMBOSIS</b>		
subjects affected / exposed	14 / 1093 (1.28%)	13 / 1048 (1.24%)
occurrences causally related to treatment / all	0 / 16	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
<b>VASCULAR PSEUDOANEURYSM</b>		
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>WOUND</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>WOUND HAEMATOMA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>WRIST FRACTURE</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>VENOUS INJURY</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Congenital, familial and genetic disorders</b>			
Tracheo-oesophageal fistula			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac disorders</b>			
Myocardial infarction			
subjects affected / exposed	16 / 1093 (1.46%)	9 / 1048 (0.86%)	
occurrences causally related to treatment / all	0 / 16	0 / 9	
deaths causally related to treatment / all	0 / 16	0 / 9	
Acute coronary syndrome			
subjects affected / exposed	5 / 1093 (0.46%)	13 / 1048 (1.24%)	
occurrences causally related to treatment / all	0 / 5	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	42 / 1093 (3.84%)	50 / 1048 (4.77%)	
occurrences causally related to treatment / all	0 / 46	0 / 59	
deaths causally related to treatment / all	0 / 6	0 / 5	
Angina pectoris			
subjects affected / exposed	9 / 1093 (0.82%)	12 / 1048 (1.15%)	
occurrences causally related to treatment / all	0 / 11	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unstable Angina			
subjects affected / exposed	3 / 1093 (0.27%)	9 / 1048 (0.86%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	

Atrial fibrillation		
subjects affected / exposed	13 / 1093 (1.19%)	21 / 1048 (2.00%)
occurrences causally related to treatment / all	0 / 19	0 / 26
deaths causally related to treatment / all	0 / 2	0 / 3
Bradycardia		
subjects affected / exposed	8 / 1093 (0.73%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiac arrest		
subjects affected / exposed	21 / 1093 (1.92%)	26 / 1048 (2.48%)
occurrences causally related to treatment / all	0 / 22	0 / 26
deaths causally related to treatment / all	0 / 17	0 / 19
Cardiac disorder		
subjects affected / exposed	6 / 1093 (0.55%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac failure		
subjects affected / exposed	7 / 1093 (0.64%)	9 / 1048 (0.86%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 4
Acute Cardiac failure		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Congestive Cardiac failure		
subjects affected / exposed	6 / 1093 (0.55%)	7 / 1048 (0.67%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 5
Cardio-respiratory arrest		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Coronary artery disease		

subjects affected / exposed	4 / 1093 (0.37%)	6 / 1048 (0.57%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Atrial flutter		
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complete Atrioventricular block		
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure chronic		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Cardiac tamponade		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		
subjects affected / exposed	6 / 1093 (0.55%)	7 / 1048 (0.67%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 5
Cardiogenic shock		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiomegaly		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hypertensive heart disease		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Intracardiac mass		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Left ventricular failure		
subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 3
Left ventricular hypertrophy		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Mitral valve disease		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Myocardial ischaemia		
subjects affected / exposed	5 / 1093 (0.46%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 3
Myocarditis		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	5 / 1093 (0.46%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal arrhythmia		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial haemorrhage		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pericarditis		

subjects affected / exposed	4 / 1093 (0.37%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Pulseless electrical activity</b>			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Supraventricular tachycardia</b>			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Tachycardia</b>			
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Trifascicular block</b>			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ventricular tachycardia</b>			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ventricular fibrillation</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nervous system disorders</b>			
<b>AMNESIA</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>APHASIA</b>			

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BALANCE DISORDER</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BALLISMUS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BASAL GANGLIA STROKE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BRAIN INJURY</b>		
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 3
<b>CAROTID ARTERY STENOSIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CENTRAL NERVOUS SYSTEM LESION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CEREBRAL HAEMORRHAGE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 2
<b>CEREBRAL INFARCTION</b>		

subjects affected / exposed	4 / 1093 (0.37%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1
<b>CEREBRAL ISCHAEMIA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CEREBROVASCULAR ACCIDENT</b>		
subjects affected / exposed	12 / 1093 (1.10%)	16 / 1048 (1.53%)
occurrences causally related to treatment / all	0 / 45	0 / 18
deaths causally related to treatment / all	0 / 8	0 / 5
<b>CEREBROVASCULAR DISORDER</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>COMA URAEMIC</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>CONSCIOUSNESS FLUCTUATING</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>CONVULSION</b>		
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DEPRESSED LEVEL OF CONSCIOUSNESS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DIZZINESS</b>		

subjects affected / exposed	8 / 1093 (0.73%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DYSARTHRIA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DYSKINESIA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>EMBOLIC CEREBRAL INFARCTION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ENCEPHALITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ENCEPHALITIS AUTOIMMUNE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ENCEPHALOPATHY</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>EPILEPSY</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GRAND MAL CONVULSION</b>		

subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GUILLAIN-BARRE SYNDROME</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HAEMORRHAGE INTRACRANIAL</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>HAEMORRHAGIC CEREBRAL INFARCTION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>HAEMORRHAGIC STROKE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>HEADACHE</b>		
subjects affected / exposed	6 / 1093 (0.55%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HEMIPARESIS</b>		
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
<b>HEPATIC ENCEPHALOPATHY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HYPERGLYCAEMIC SEIZURE</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HYPERTENSIVE ENCEPHALOPATHY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HYPOAESTHESIA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HYPOGLYCAEMIC SEIZURE</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INTRAVENTRICULAR HAEMORRHAGE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ISCHAEMIC STROKE</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LACUNAR INFARCTION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LETHARGY</b>		
subjects affected / exposed	5 / 1093 (0.46%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
<b>LOSS OF CONSCIOUSNESS</b>		

subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MEMORY IMPAIRMENT</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MERALGIA PARAESTHETICA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MIGRAINE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MOVEMENT DISORDER</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>MYOCLONUS</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MYXOEDEMA COMA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NERVOUS SYSTEM DISORDER</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>NEUROLOGICAL SYMPTOM</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NEUROPATHY PERIPHERAL</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERONEAL NERVE PALSY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PRESYNCOPE</b>		
subjects affected / exposed	7 / 1093 (0.64%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SEIZURE LIKE PHENOMENA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>SENSORY LOSS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SOMNOLENCE</b>		
subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SPEECH DISORDER</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SPINAL CORD COMPRESSION</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SYNCOPE</b>			
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>TRANSIENT ISCHAEMIC ATTACK</b>			
subjects affected / exposed	11 / 1093 (1.01%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>TREMOR</b>			
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>UNRESPONSIVE TO STIMULI</b>			
subjects affected / exposed	7 / 1093 (0.64%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>VASCULAR DEMENTIA</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>VIITH NERVE PARALYSIS</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	8 / 1093 (0.73%)	13 / 1048 (1.24%)	
occurrences causally related to treatment / all	0 / 8	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Lymphadenectomy</b>			

subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nephrogenic anaemia</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pancytopenia</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thrombocytopenia</b>			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ear and labyrinth disorders</b>			
<b>Vertigo</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Eye disorders</b>			
<b>Amaurosis fugax</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cataract</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Eye pain</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyphaema</b>			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Retinal haemorrhage</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Retinal vascular occlusion</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Retinal artery occlusion</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Visual impairment</b>			
subjects affected / exposed	1 / 1093 (0.09%)	11 / 1048 (1.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vitreous haemorrhage</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal disorders</b>			
<b>Abdominal adhesions</b>			
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Abdominal pain</b>			
subjects affected / exposed	23 / 1093 (2.10%)	14 / 1048 (1.34%)	
occurrences causally related to treatment / all	0 / 28	0 / 15	
deaths causally related to treatment / all	0 / 4	0 / 1	
<b>Abdominal distension</b>			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain lower		
subjects affected / exposed	0 / 1093 (0.00%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal strangulated hernia		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Bowel movement irregularity		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coeliac disease		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Colitis		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
colonic stenosis		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	6 / 1093 (0.55%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroparesis		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		

subjects affected / exposed	11 / 1093 (1.01%)	13 / 1048 (1.24%)
occurrences causally related to treatment / all	0 / 12	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea haemorrhagic		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faeces discoloured		

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
faecal incontinence			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric disorder			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric perforation			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	3 / 1093 (0.27%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			

subjects affected / exposed	3 / 1093 (0.27%)	9 / 1048 (0.86%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Gastrointestinal motility disorder</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrointestinal hypermotility</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrointestinal angiodysplasia</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrointestinal pain</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>gastrooesophagitis</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Gastrooesophageal reflux disease</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematemesis</b>		
subjects affected / exposed	5 / 1093 (0.46%)	6 / 1048 (0.57%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Haemorrhoidal haemorrhage</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhoids</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ileitis</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Impaired gastric emptying</b>		
subjects affected / exposed	6 / 1093 (0.55%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal fistula</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Inguinal hernia</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal ischaemia</b>		
subjects affected / exposed	7 / 1093 (0.64%)	8 / 1048 (0.76%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 4	0 / 5
<b>Intestinal obstruction</b>		
subjects affected / exposed	3 / 1093 (0.27%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 3
<b>Irritable bowel syndrome</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Large intestine perforation		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malabsorption		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	7 / 1093 (0.64%)	7 / 1048 (0.67%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Megacolon		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mouth ulceration		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal rupture		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatic mass		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatitis chronic		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Proctitis		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	7 / 1093 (0.64%)	11 / 1048 (1.05%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 2
Retching		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal fibrosis		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Small intestinal obstruction		
subjects affected / exposed	6 / 1093 (0.55%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Steatorrhoea		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	3 / 1093 (0.27%)	10 / 1048 (0.95%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Umbilical hernia, obstructive		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	26 / 1093 (2.38%)	18 / 1048 (1.72%)	
occurrences causally related to treatment / all	0 / 30	0 / 20	
deaths causally related to treatment / all	0 / 3	0 / 0	
Skin and subcutaneous tissue disorders			
COLD SWEAT			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DECUBITUS ULCER			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETIC FOOT			
subjects affected / exposed	7 / 1093 (0.64%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
DIABETIC ULCER			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRY GANGRENE			

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>HYPERHIDROSIS</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>RASH</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>RASH MACULO-PAPULAR</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SKIN NECROSIS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SKIN REACTION</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SKIN SWELLING</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SKIN ULCER</b>			
subjects affected / exposed	11 / 1093 (1.01%)	6 / 1048 (0.57%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal and urinary disorders</b>			
<b>AZOTAEMIA</b>			

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BLADDER OUTLET OBSTRUCTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DYSURIA</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HAEMATURIA</b>		
subjects affected / exposed	10 / 1093 (0.91%)	10 / 1048 (0.95%)
occurrences causally related to treatment / all	0 / 11	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MICTURITION URGENCY</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NEPHROLITHIASIS</b>		
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NEPHROTIC SYNDROME</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>OBSTRUCTIVE UROPATHY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RENAL COLIC</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RENAL CYST HAEMORRHAGE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RENAL FAILURE</b>		
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
<b>ACUTE RENAL FAILURE</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CHRONIC RENAL FAILURE</b>		
subjects affected / exposed	8 / 1093 (0.73%)	27 / 1048 (2.58%)
occurrences causally related to treatment / all	0 / 8	0 / 27
deaths causally related to treatment / all	0 / 7	0 / 21
<b>RENAL IMPAIRMENT</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>RENAL MASS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RENAL PAIN</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>URINARY RETENTION</b>		

subjects affected / exposed	4 / 1093 (0.37%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>URINARY TRACT DISORDER</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>URINARY TRACT OBSTRUCTION</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>PRIAPISM</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>TESTICULAR PAIN</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Endocrine disorders</b>			
<b>Hyperparathyroidism tertiary</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>ARTHRALGIA</b>			
subjects affected / exposed	1 / 1093 (0.09%)	7 / 1048 (0.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ARTHRITIS</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

ARTHROPATHY		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
BACK PAIN		
subjects affected / exposed	3 / 1093 (0.27%)	6 / 1048 (0.57%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
BURSITIS		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
COCCYDYNIA		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
COSTOCHONDRITIS		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
FLANK PAIN		
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
FRACTURE NONUNION		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
GROIN PAIN		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HAEMARTHROSIS		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>JOINT SWELLING</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MOBILITY DECREASED</b>		
subjects affected / exposed	4 / 1093 (0.37%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
<b>MUSCLE TWITCHING</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MUSCULAR WEAKNESS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2
<b>MUSCULOSKELETAL CHEST PAIN</b>		
subjects affected / exposed	6 / 1093 (0.55%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MUSCULOSKELETAL PAIN</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MUSCULOSKELETAL STIFFNESS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MYOPATHY</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NECK PAIN</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NEUROPATHIC ARTHROPATHY</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>OSTEOARTHRITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>OSTEONECROSIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PAIN IN EXTREMITY</b>		
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POLYMYALGIA RHEUMATICA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RHEUMATOID ARTHRITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>SPINAL OSTEOARTHRITIS</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>SYSTEMIC LUPUS ERYTHEMATOSUS</b>			
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>ABDOMINAL SEPSIS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ABSCESS</b>			
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ABSCESS LIMB</b>			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ANAL ABSCESS</b>			
subjects affected / exposed	0 / 1093 (0.00%)	4 / 1048 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>APPENDICITIS</b>			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>APPENDICITIS PERFORATED</b>			
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>ARTERIOVENOUS FISTULA SITE INFECTION</b>			

subjects affected / exposed	8 / 1093 (0.73%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ARTERIOVENOUS GRAFT SITE INFECTION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ARTHRITIS BACTERIAL</b>		
subjects affected / exposed	4 / 1093 (0.37%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ARTHRITIS INFECTIVE</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BACTERAEMIA</b>		
subjects affected / exposed	4 / 1093 (0.37%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BACTERIAL INFECTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BACTERIAL SEPSIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>BILIARY SEPSIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	6 / 1048 (0.57%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BRONCHIOLITIS</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BRONCHITIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>BRONCHOPNEUMONIA</b>		
subjects affected / exposed	2 / 1093 (0.18%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2
<b>CAMPYLOBACTER GASTROENTERITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CAMPYLOBACTER INFECTION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CAMPYLOBACTER SEPSIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CARDIAC VALVE VEGETATION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>CATHETER SITE INFECTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CELLULITIS</b>		

subjects affected / exposed	18 / 1093 (1.65%)	24 / 1048 (2.29%)
occurrences causally related to treatment / all	0 / 18	0 / 32
deaths causally related to treatment / all	0 / 0	0 / 2
<b>CELLULITIS GANGRENOUS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CENTRAL NERVOUS SYSTEM INFECTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CLOSTRIDIAL INFECTION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CLOSTRIDIUM DIFFICILE COLITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CYSTITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DEVICE RELATED INFECTION</b>		
subjects affected / exposed	23 / 1093 (2.10%)	20 / 1048 (1.91%)
occurrences causally related to treatment / all	0 / 25	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DEVICE RELATED SEPSIS</b>		
subjects affected / exposed	25 / 1093 (2.29%)	15 / 1048 (1.43%)
occurrences causally related to treatment / all	0 / 27	0 / 18
deaths causally related to treatment / all	0 / 1	0 / 2
<b>DIABETIC FOOT INFECTION</b>		

subjects affected / exposed	0 / 1093 (0.00%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DIVERTICULITIS</b>		
subjects affected / exposed	3 / 1093 (0.27%)	4 / 1048 (0.38%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DIARRHOEA INFECTIOUS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>EMPHYSEMATOUS PYELONEPHRITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>EMPHYEMA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ENCEPHALITIS VIRAL</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>ENDOCARDITIS1</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>ENTEROBACTER SEPSIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ENTEROCOCCAL INFECTION</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ENTEROCOCCAL SEPSIS</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>ESCHERICHIA BACTERAEMIA</b>		
subjects affected / exposed	6 / 1093 (0.55%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ESCHERICHIA INFECTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ESCHERICHIA URINARY TRACT INFECTION</b>		
subjects affected / exposed	3 / 1093 (0.27%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GALLBLADDER ABSCESS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GANGRENE</b>		
subjects affected / exposed	10 / 1093 (0.91%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 11	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 0
<b>GASTROENTERITIS</b>		
subjects affected / exposed	11 / 1093 (1.01%)	11 / 1048 (1.05%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GASTROENTERITIS VIRAL</b>		

subjects affected / exposed	4 / 1093 (0.37%)	6 / 1048 (0.57%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GRAFT INFECTION</b>		
subjects affected / exposed	3 / 1093 (0.27%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>GROIN ABSCESS</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>H1N1 INFLUENZA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HAEMATOMA INFECTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INFECTED SKIN ULCER</b>		
subjects affected / exposed	6 / 1093 (0.55%)	6 / 1048 (0.57%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INFECTION</b>		
subjects affected / exposed	11 / 1093 (1.01%)	8 / 1048 (0.76%)
occurrences causally related to treatment / all	1 / 12	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 0
<b>INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE</b>		
subjects affected / exposed	4 / 1093 (0.37%)	11 / 1048 (1.05%)
occurrences causally related to treatment / all	0 / 5	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 4
<b>INFLUENZA</b>		

subjects affected / exposed	8 / 1093 (0.73%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0
<b>INTERVERTEBRAL DISCITIS</b>		
subjects affected / exposed	4 / 1093 (0.37%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>KLEBSIELLA SEPSIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LIVER ABSCESS</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LOBAR PNEUMONIA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
<b>LOCALISED INFECTION</b>		
subjects affected / exposed	10 / 1093 (0.91%)	12 / 1048 (1.15%)
occurrences causally related to treatment / all	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 0
<b>LOWER RESPIRATORY TRACT INFECTION</b>		
subjects affected / exposed	77 / 1093 (7.04%)	94 / 1048 (8.97%)
occurrences causally related to treatment / all	0 / 92	0 / 113
deaths causally related to treatment / all	0 / 4	0 / 11
<b>INJECTION SITE INFECTION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INFECTIVE EXACERBATION OF BRONCHIECTASIS</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>INFECTIVE ANEURYSM</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INFECTIOUS PLEURAL EFFUSION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>INFECTED FISTULA</b>		
subjects affected / exposed	4 / 1093 (0.37%)	6 / 1048 (0.57%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>HERPES ZOSTER</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LOWER RESPIRATORY TRACT INFECTION VIRAL</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LUNG INFECTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>LUNG INFECTION PSEUDOMONAL</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>METAPNEUMOVIRUS INFECTION</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>NEUTROPENIC SEPSIS</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>OESOPHAGEAL CANDIDIASIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ORAL CANDIDIASIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>OSTEOMYELITIS</b>		
subjects affected / exposed	8 / 1093 (0.73%)	17 / 1048 (1.62%)
occurrences causally related to treatment / all	0 / 8	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 4
<b>OTITIS EXTERNA</b>		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>PAROTITIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERIHEPATIC ABSCESS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PERITONITIS</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PILONIDAL CYST</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PNEUMOCOCCAL SEPSIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PNEUMOCYSTIS JIROVECI PNEUMONIA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PNEUMONIA</b>		
subjects affected / exposed	72 / 1093 (6.59%)	70 / 1048 (6.68%)
occurrences causally related to treatment / all	0 / 83	0 / 85
deaths causally related to treatment / all	0 / 13	0 / 9
<b>PNEUMONIA BACTERIAL</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PNEUMONIA INFLUENZAL</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PNEUMONIA KLEBSIELLA</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PNEUMONIA VIRAL</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POST PROCEDURAL INFECTION</b>		
subjects affected / exposed	3 / 1093 (0.27%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POST PROCEDURAL PNEUMONIA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>POST PROCEDURAL SEPSIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
<b>POSTOPERATIVE WOUND INFECTION</b>		
subjects affected / exposed	4 / 1093 (0.37%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
<b>PSEUDOMEMBRANOUS COLITIS</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PSOAS ABSCESS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PULMONARY SEPSIS</b>		
subjects affected / exposed	8 / 1093 (0.73%)	10 / 1048 (0.95%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 3	0 / 1
<b>PULMONARY TUBERCULOSIS</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PYELONEPHRITIS</b>		
subjects affected / exposed	4 / 1093 (0.37%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>PYONEPHROSIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RENAL ABSCESS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RENAL CYST INFECTION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RESPIRATORY SYNCYTIAL VIRUS INFECTION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RESPIRATORY TRACT INFECTION VIRAL</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RESPIRATORY TRACT INFECTION</b>		
subjects affected / exposed	4 / 1093 (0.37%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>RHINOVIRUS INFECTION</b>		

subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SEPSIS</b>		
subjects affected / exposed	60 / 1093 (5.49%)	57 / 1048 (5.44%)
occurrences causally related to treatment / all	0 / 71	0 / 61
deaths causally related to treatment / all	0 / 16	0 / 13
<b>SEPTIC ARTHRITIS STAPHYLOCOCCAL</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SEPTIC EMBOLUS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SEPTIC ENCEPHALOPATHY</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>SEPTIC NECROSIS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SEPTIC SHOCK</b>		
subjects affected / exposed	2 / 1093 (0.18%)	5 / 1048 (0.48%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 3
<b>SOFT TISSUE INFECTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SPLENIC ABSCESS</b>		

subjects affected / exposed	0 / 1093 (0.00%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
<b>STAPHYLOCOCCAL BACTERAEMIA</b>		
subjects affected / exposed	8 / 1093 (0.73%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
<b>STAPHYLOCOCCAL INFECTION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>STAPHYLOCOCCAL SEPSIS</b>		
subjects affected / exposed	5 / 1093 (0.46%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	2 / 5	0 / 1
deaths causally related to treatment / all	2 / 2	0 / 0
<b>STREPTOCOCCAL SEPSIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>SUBCUTANEOUS ABSCESS</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>TONSILLITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>TOOTH ABSCESS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>TUBERCULOSIS</b>		

subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>UPPER RESPIRATORY TRACT INFECTION</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>URETHRITIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>URINARY TRACT INFECTION</b>		
subjects affected / exposed	29 / 1093 (2.65%)	18 / 1048 (1.72%)
occurrences causally related to treatment / all	0 / 29	0 / 18
deaths causally related to treatment / all	0 / 2	0 / 0
<b>UROSEPSIS</b>		
subjects affected / exposed	18 / 1093 (1.65%)	11 / 1048 (1.05%)
occurrences causally related to treatment / all	0 / 20	0 / 12
deaths causally related to treatment / all	0 / 2	0 / 1
<b>URINARY TRACT INFECTION PSEUDOMONAL</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>VIRAL INFECTION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>WOUND INFECTION</b>		
subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metabolism and nutrition disorders</b>		

FLUID OVERLOAD		
subjects affected / exposed	41 / 1093 (3.75%)	63 / 1048 (6.01%)
occurrences causally related to treatment / all	0 / 51	0 / 79
deaths causally related to treatment / all	0 / 2	0 / 4
GOUT		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
HYPERCALCAEMIA		
subjects affected / exposed	2 / 1093 (0.18%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HYPERGLYCAEMIA		
subjects affected / exposed	9 / 1093 (0.82%)	9 / 1048 (0.86%)
occurrences causally related to treatment / all	0 / 9	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
HYPERKALAEMIA		
subjects affected / exposed	29 / 1093 (2.65%)	28 / 1048 (2.67%)
occurrences causally related to treatment / all	0 / 35	0 / 36
deaths causally related to treatment / all	0 / 3	0 / 1
HYPOCALCAEMIA		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
HYPOGLYCAEMIA		
subjects affected / exposed	10 / 1093 (0.91%)	20 / 1048 (1.91%)
occurrences causally related to treatment / all	0 / 11	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
HYPONATRAEMIA		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
HYPOVOLAEMIA		

subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>MALNUTRITION</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>METABOLIC ACIDOSIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>TYPE 1 DIABETES MELLITUS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>ACIDOSIS</b>		
subjects affected / exposed	1 / 1093 (0.09%)	0 / 1048 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CACHEXIA</b>		
subjects affected / exposed	0 / 1093 (0.00%)	1 / 1048 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>CALCIPHYLAXIS</b>		
subjects affected / exposed	3 / 1093 (0.27%)	3 / 1048 (0.29%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
<b>DECREASED APPETITE</b>		
subjects affected / exposed	1 / 1093 (0.09%)	2 / 1048 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>DEHYDRATION</b>		

subjects affected / exposed	2 / 1093 (0.18%)	2 / 1048 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>DIABETES MELLITUS</b>			
subjects affected / exposed	2 / 1093 (0.18%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 2	
<b>INADEQUATE CONTROL DIABETES MELLITUS</b>			
subjects affected / exposed	1 / 1093 (0.09%)	5 / 1048 (0.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>DIABETIC KETOACIDOSIS</b>			
subjects affected / exposed	9 / 1093 (0.82%)	3 / 1048 (0.29%)	
occurrences causally related to treatment / all	0 / 13	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 1	
<b>ELECTROLYTE IMBALANCE</b>			
subjects affected / exposed	1 / 1093 (0.09%)	1 / 1048 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

<b>Non-serious adverse events</b>	Proactive IV Iron	Reactive IV Iron	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1093 (0.00%)	0 / 1048 (0.00%)	

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported

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### **Online references**

<http://www.ncbi.nlm.nih.gov/pubmed/30641026>