



Clinical trial results:

Evaluation of Insuman Implantable 400 IU/ml in Patients with Type 1 Diabetes Treated with the Medtronic MiniMed Implantable Pump System Using Insuplant 400 IU/mL

Summary

EudraCT number	2010-021373-37
Trial protocol	FR NL SE BE
Global end of trial date	01 February 2018

Results information

Result version number	v1 (current)
This version publication date	14 February 2019
First version publication date	14 February 2019

Trial information

Trial identification

Sponsor protocol code	HUBIN_L_05335
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01194882
WHO universal trial number (UTN)	U1111-1116-7658
Other trial identifiers	STUDY NAME: HUBIN

Notes:

Sponsors

Sponsor organisation name	Sanofi aventis recherche & développement
Sponsor organisation address	1 avenue Pierre Brossolette, Chilly-Mazarin, France, 91380
Public contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com

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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 January 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 February 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare Insuman Implantable 400 International Units (IU)/ml versus Insuplant 400 IU/ml with respect to the pump refill accuracy during a 4 refill cycle period (comparative phase = 160 ± 20 days); To assess efficacy measured by haemoglobin glycosylated (HBA1c) change in Insuman Implantable 400 IU/ml group versus Insuplant 400 IU/ml group after a 4 refill cycle period (comparative phase = 160 ± 20 days).

Protection of trial subjects:

Subjects were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the subject and considering the local culture. During the course of the trial, subjects were provided with individual subject cards indicating the nature of the trial the subject is participating, contact details and any information needed in the event of a medical emergency. Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 November 2010
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	Netherlands: 75
Country: Number of subjects enrolled	Sweden: 29
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	France: 365
Worldwide total number of subjects	472
EEA total number of subjects	472

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)	2
Adults (18-64 years)	403
From 65 to 84 years	67
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 17 sites in 4 countries between 16 November 2010 and 01 February 2018. A total of 472 subjects were included in study which consisted of 3 phases: comparative phase, non-comparative phase and treatment phase with Insuman Implantable.

Pre-assignment

Screening details:

Of 472 subjects, 169 subjects were randomized in 1:1 ratio (Insuman Implantable : Insuplant) in comparative phase & 307 were included in non-comparative and treatment phase with Insuman Implantable. i.e. out of the included subjects, two-third subjects participated in two phases and one-third participated only in the Insuman non-comparative phase.

Period 1

Period 1 title	Overall Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Arm title	All Subjects
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Arm description:

Subjects earlier treated with Insuplant 400 International Units Per Millilitre (IU/mL) were included in the study and received Insuman Implantable 400 IU/mL or Insuplant IU/mL for 4 refill cycles in comparative phase and Insuplant 400 IU/mL for 4 refill cycles as per standard care in non-comparative phase. Comparative phase was followed by a treatment phase with only Insuman Implantable 400 IU/mL until its availability on the market. Each pump refill cycle was 40 ± 5 days.

Arm type	Experimental
Investigational medicinal product name	Insuman Implantable
Investigational medicinal product code	
Other name	Human insulin (rapid acting)
Pharmaceutical forms	Solution for infusion
Routes of administration	Intraperitoneal use

Dosage and administration details:

The glucose targets and insulin dose were established by the Investigator on a subject basis and as per American Diabetes Association guidelines. Treatments was administered by Continuous IntraPeritoneal Insulin Infusion (CIPII) through an implantable pump system.

Investigational medicinal product name	Insuplant
Investigational medicinal product code	
Other name	Human insulin semi synthetic porcine derived
Pharmaceutical forms	Solution for infusion
Routes of administration	Intraperitoneal use

Dosage and administration details:

The glucose targets and insulin dose were established by the Investigator on a subject basis and as per American Diabetes Association guidelines. Treatments was administered by CIPII through an implantable pump system.

Number of subjects in period 1	All Subjects
Started	472
Completed	356
Not completed	116
Other than specified above	26
Consent withdrawn by subject	18
Adverse Event	65
Lost to follow-up	1
Lack of efficacy	6

Baseline characteristics

Reporting groups

Reporting group title	All Subjects
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Reporting group description:

Subjects earlier treated with Insuplant 400 International Units Per Millilitre (IU/mL) were included in the study and received Insuman Implantable 400 IU/mL or Insuplant IU/mL for 4 refill cycles in comparative phase and Insuplant 400 IU/mL for 4 refill cycles as per standard care in non-comparative phase. Comparative phase was followed by a treatment phase with only Insuman Implantable 400 IU/mL until its availability on the market. Each pump refill cycle was 40±5 days.

Reporting group values	All Subjects	Total	
Number of subjects	472	472	
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	50.18		
standard deviation	± 12.82	-	
Gender categorical			
Units: Subjects			
Female	298	298	
Male	174	174	
Baseline HbA1c			
Data for baseline HbA1c is reported for 365 subjects.			
Units: Percentage of HbA1c			
arithmetic mean	7.96		
standard deviation	± 1.28	-	
Actual Baseline Insulin Dose			
Data for actual baseline insulin dose is reported for 223 subjects.			
Units: IU/day			
arithmetic mean	49.90		
standard deviation	± 25.96	-	

End points

End points reporting groups

Reporting group title	All Subjects
Reporting group description: Subjects earlier treated with Insuplant 400 International Units Per Millilitre (IU/mL) were included in the study and received Insuman Implantable 400 IU/mL or Insuplant IU/mL for 4 refill cycles in comparative phase and Insuplant 400 IU/mL for 4 refill cycles as per standard care in non-comparative phase. Comparative phase was followed by a treatment phase with only Insuman Implantable 400 IU/mL until its availability on the market. Each pump refill cycle was 40±5 days.	
Subject analysis set title	Insuman (Comparative Phase)
Subject analysis set type	Per protocol
Subject analysis set description: Subjects received Insuman Implantable 400 IU/mL for 4 refill cycles i.e. 6 Months by continuous intraperitoneal insulin infusion through an implantable pump system.	
Subject analysis set title	Insuplant (Comparative Phase)
Subject analysis set type	Per protocol
Subject analysis set description: Subjects received Insuplant 400 IU/mL for 4 refill cycles i.e. 6 Months by continuous intraperitoneal insulin infusion through an implantable pump system.	
Subject analysis set title	Insuplant Phase
Subject analysis set type	Per protocol
Subject analysis set description: Subjects (who were not included in comparative phase) received Insuplant 400 IU/mL for 4 refill cycles as per standard care by continuous intraperitoneal insulin infusion through an implantable pump system.	
Subject analysis set title	Insuman Phase
Subject analysis set type	Per protocol
Subject analysis set description: Subjects received Insuman 400 IU/mL for 4 refill cycles as per standard care by continuous intraperitoneal insulin infusion through an implantable pump system and avoided pump ex-plantation.	

Primary: Percentage Refill Accuracy After 4 Refill Cycles: Modified Intent to Treat (mITT) Population

End point title	Percentage Refill Accuracy After 4 Refill Cycles: Modified Intent to Treat (mITT) Population
End point description: Refill accuracy was calculated as a percentage difference between the theoretical refill volume calculated by the personal pump communicator (PPC) using programmed values and the actual refill volume used by weight measurement after 4 refill cycles. Analysis was performed on mITT population for refill accuracy. mITT population included subjects who had given their informed consent, for whom there was confirmation of successful allocation of a randomization number through the study treatment allocation system, and who received at least one administration of the study drug and had an evaluation for each primary outcome. Subjects who had no available or no valid post-baseline refill value were excluded from the mITT population for refill accuracy.	
End point type	Primary
End point timeframe: From baseline up to refill cycle 4 (i.e. Month 6)	

End point values	Insuman (Comparative Phase)	Insuplant (Comparative Phase)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	64		
Units: percentage accuracy				
arithmetic mean (standard deviation)	0.06 (± 8.00)	2.82 (± 5.91)		

Statistical analyses

Statistical analysis title	Comparative Phase: Insuman vs Insuplant
Statistical analysis description: Analysis was performed using Analysis of variance (ANOVA) method.	
Comparison groups	Insuman (Comparative Phase) v Insuplant (Comparative Phase)
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
P-value	= 0.0273
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.21
upper limit	-0.31
Variability estimate	Standard error of the mean
Dispersion value	1.24

Notes:

[1] - Non-inferiority of Insuman Implantable over Insuplant was demonstrated if upper limit of 2-sided 95% confidence interval (CI) of the intergroup difference was <5%.

Primary: Percentage Refill Accuracy After 4 Refill Cycles: Per Protocol (PP) Population

End point title	Percentage Refill Accuracy After 4 Refill Cycles: Per Protocol (PP) Population
End point description: Refill accuracy was calculated as a percentage difference between the theoretical refill volume calculated by the PPC using programmed values and the actual refill volume used by weight measurement after 4 refill cycles. Analysis was performed on PP population for refill accuracy. PP population was a subset of mITT population without major protocol violations for each primary parameter.	
End point type	Primary
End point timeframe: From baseline up to refill cycle 4 (i.e. Month 6)	

End point values	Insuman (Comparative Phase)	Insuplant (Comparative Phase)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	56		
Units: percentage accuracy				
arithmetic mean (standard deviation)	-0.08 (± 8.14)	3.07 (± 6.17)		

Statistical analyses

Statistical analysis title	Comparative Phase: Insuman vs Insuplant
Statistical analysis description: Analysis was performed using ANOVA method.	
Comparison groups	Insuman (Comparative Phase) v Insuplant (Comparative Phase)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[2]
P-value	= 0.0205
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-3.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.81
upper limit	-0.5
Variability estimate	Standard error of the mean
Dispersion value	1.34

Notes:

[2] - Non-inferiority of Insuman Implantable over Insuplant was demonstrated if upper limit of 2-sided 95% confidence interval (CI) of the intergroup difference was <5%.

Primary: Change From Baseline in HbA1c to Month 6: mITT Population

End point title	Change From Baseline in HbA1c to Month 6: mITT Population
End point description: Change in HbA1c was calculated by subtracting baseline value from Month 6 value. Analysis was performed on mITT population for HbA1c.	
End point type	Primary
End point timeframe: Baseline, Month 6	

End point values	Insuman (Comparative Phase)	Insuplant (Comparative Phase)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	84	84		
Units: percentage of HbA1c				
arithmetic mean (standard deviation)	-0.27 (± 0.70)	-0.20 (± 0.79)		

Statistical analyses

Statistical analysis title	Comparative Phase: Insuman vs Insuplant
Statistical analysis description: Analysis was performed using ANOVA method.	
Comparison groups	Insuplant (Comparative Phase) v Insuman (Comparative Phase)
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[3]
P-value	= 0.543
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.16
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:

[3] - Non-inferiority of Insuman Implantable over Insuplant was demonstrated if upper limit of 2-sided 95% CI of the inter group difference was 0.4%.

Primary: Change From Baseline in HbA1c to Month 6: PP Population

End point title	Change From Baseline in HbA1c to Month 6: PP Population
End point description: Change in HbA1c was calculated by subtracting baseline value from Month 6 value. Analysis was performed on PP population for HbA1c.	
End point type	Primary
End point timeframe: Baseline, Month 6	

End point values	Insuman (Comparative Phase)	Insuplant (Comparative Phase)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	75	69		
Units: percentage of HbA1c				
arithmetic mean (standard deviation)	-0.25 (± 0.67)	-0.12 (± 0.74)		

Statistical analyses

Statistical analysis title	Comparative Phase: Insuman vs Insuplant
Statistical analysis description: Analysis was performed using ANOVA method.	
Comparison groups	Insuman (Comparative Phase) v Insuplant (Comparative Phase)
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[4]
P-value	= 0.2808
Method	ANOVA
Parameter estimate	Mean difference (net)
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	0.11
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:

[4] - Non-inferiority of Insuman Implantable over Insuplant was demonstrated if upper limit of 2-sided 95% CI of the inter group difference was 0.4%.

Secondary: Actual Daily Insulin Dose at Month 6: mITT Population

End point title	Actual Daily Insulin Dose at Month 6: mITT Population
End point description: Actual daily insulin doses were calculated at each refill from actual amount used after conversion in International Units (IU), and reported to the time between the refill and the previous refill in days. Analysis was performed on mITT population for HbA1c. Here "number analyzed" signifies number of subjects with available data for this end point.	
End point type	Secondary
End point timeframe: Month 6	

End point values	Insuman (Comparative Phase)	Insuplant (Comparative Phase)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	61	61		
Units: IU/day				
arithmetic mean (standard deviation)	56.72 ($\pm$ 23.16)	54.30 ($\pm$ 22.86)		

Statistical analyses

No statistical analyses for this end point

Secondary: Actual Daily Insulin Dose at Month 6: PP Population

End point title	Actual Daily Insulin Dose at Month 6: PP Population
End point description: Actual daily insulin doses were calculated at each refill from actual amount used after conversion in IU, and reported to the time between the refill and the previous refill in days. Analysis was performed on PP population for HbA1c. Here "number analyzed" signifies number of subjects with available data for this endpoint.	
End point type	Secondary
End point timeframe: Month 6	

End point values	Insuman (Comparative Phase)	Insuplant (Comparative Phase)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	57	53		
Units: IU/day				
arithmetic mean (standard deviation)	56.24 ($\pm$ 21.57)	55.80 ($\pm$ 23.68)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With At Least One Severe Hypoglycemic Events

End point title	Number of Subjects With At Least One Severe Hypoglycemic Events
End point description: Severe hypoglycemia was an event in which the subject required the assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions. Diurnal (day-time) hypoglycaemia occurring during the waking period and nocturnal hypoglycaemia, which occurred while the subject was asleep, after bedtime and before getting up in the morning. Analysis was performed on safety population composed of all randomized subjects exposed to the study drug, i.e. who received at least one administration of the study drug.	
End point type	Secondary

End point timeframe:

From Baseline up to Month 6

End point values	Insuman (Comparative Phase)	Insuplant (Comparative Phase)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	84	84		
Units: subjects				
number (not applicable)				
At least one severe hypoglycaemia	12	11		
At least one nocturnal severe hypoglycaemia	1	3		
At least one diurnal severe hypoglycaemia	10	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With At Least One Hyperglycemia With Ketonemia

End point title	Number of Subjects With At Least One Hyperglycemia With Ketonemia
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End point description:

Hyperglycaemia is defined as blood glucose value above 300 mg/dL (16.7 mmol/L) with no apparent medical, dietary or insulin dosage reason. Subjects with at least one hyperglycaemia with ketonemia and ketonemia > 0.5 mmol/l were reported. Analysis was performed on safety population.

End point type	Secondary
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End point timeframe:

From Baseline up to Month 6

End point values	Insuman (Comparative Phase)	Insuplant (Comparative Phase)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	84	84		
Units: subjects				
number (not applicable)				
At least one hyperglycaemia with ketonemia	13	15		
At least 1 hyperglycaemia with ketonemia>0.5mmol/l	2	4		

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All Adverse Events (AEs) were collected from signature of informed consent form until the end of the study i.e. end of Insuman non comparative phase (maximum treatment exposure: 6.6 years) regardless of seriousness/relationship to investigational product.

Adverse event reporting additional description:

Reported AEs & deaths are treatment-emergent AEs that is AEs that developed/worsened & deaths occurred during 'on treatment period' (time interval between first Insuman administration & 10 days after last study drug administration). Safety population. 3 subjects from comparative phase (1 from Insuman & 2 from Insuplant) were not included in analysis.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.0
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Reporting groups

Reporting group title	Insuman comparative phase
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Reporting group description:

Subjects received Insuman Implantable 400 IU/mL for 4 refill cycles i.e. 6 Months by continuous intraperitoneal insulin infusion through an implantable pump system (Medtronic Minimed implantable pump). Out of 84 subjects, 1 subject was not included in safety population.

Reporting group title	Insuplant comparative phase
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Reporting group description:

Subjects received Insuplant 400 IU/mL for 4 refill cycles i.e. 6 Months by continuous intraperitoneal insulin infusion through an implantable pump system (Medtronic Minimed implantable pump). Out of 84 subjects, 2 subjects were not included in safety population.

Reporting group title	Insuplant phase
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Reporting group description:

Subjects who were not included in comparative phase, received Insuplant 400 IU/mL for 4 refill cycles as per standard care by continuous intraperitoneal insulin infusion through an implantable pump system (Medtronic Minimed implantable pump).

Reporting group title	Insuman phase
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Reporting group description:

Subjects received Insuman 400 IU/mL for 4 refill cycles as per standard care by continuous intraperitoneal insulin infusion through an implantable pump system (Medtronic Minimed implantable pump) and avoided pump ex-plantation.

Serious adverse events	Insuman comparative phase	Insuplant comparative phase	Insuplant phase
Total subjects affected by serious adverse events			
subjects affected / exposed	64 / 83 (77.11%)	61 / 82 (74.39%)	113 / 159 (71.07%)
number of deaths (all causes)	1	2	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			

subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Cancer			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	3 / 159 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Neoplasm			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's Disease Lymphocyte Depletion Type Stage Iii			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Adenocarcinoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic Gastric Cancer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			

subjects affected / exposed	2 / 83 (2.41%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cancer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Adventitial Cystic Disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Disorder			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Insufficiency			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Occlusive Disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteritis			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism Venous			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent Claudication			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic Hypotension			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Occlusion			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Stenosis			
subjects affected / exposed	2 / 83 (2.41%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Ischaemia			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior Vena Cava Stenosis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Arterial Therapeutic Procedure			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Prosthesis Implantation			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Caesarean Section			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract Operation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystectomy			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Angioplasty			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Bypass			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Revascularisation			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyst Removal			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Finger Repair Operation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Bypass			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hospitalisation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hysterectomy			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leg Amputation			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mammoplasty			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Change			
subjects affected / exposed	3 / 83 (3.61%)	7 / 82 (8.54%)	11 / 159 (6.92%)
occurrences causally related to treatment / all	3 / 4	8 / 8	10 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Implantation			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Removal			
subjects affected / exposed	1 / 83 (1.20%)	3 / 82 (3.66%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cystectomy			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreas Transplant			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Percutaneous Coronary Intervention			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Nerve Operation			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Revascularisation			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic Operation			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Sympathetic Nerve Ablation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Transplant			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Operation			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Repair			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Operation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent Placement			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical Vascular Shunt			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Operation			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toe Amputation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Delivery			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Live Birth			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-Eclampsia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unintended Pregnancy			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter Site Pain			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General Physical Health Deterioration			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised Oedema			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granuloma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Healing			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	2 / 83 (2.41%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Site Atrophy			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Site Erosion			
subjects affected / exposed	2 / 83 (2.41%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	2 / 2	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Site Erythema			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Site Haemorrhage			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Site Inflammation			
subjects affected / exposed	3 / 83 (3.61%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	3 / 3	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Site Pain			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Due To Cardiac Disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
subjects affected / exposed	2 / 83 (2.41%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolapse			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Swelling			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Amyloidosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic Shock			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Hypersensitivity			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insulin Autoimmune Syndrome			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast Enlargement			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital Prolapse			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic Ovarian Cyst			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menometrorrhagia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Polyp			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Pulmonary Oedema			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea Exertional			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal Pain			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Oedema			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep Apnoea Syndrome			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	3 / 83 (3.61%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major Depression			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mania			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric Decompensation			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep Disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood Glucose Fluctuation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Glucose Increased			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular Evaluation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart Rate Increased			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laparoscopy			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Observation			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight Increased			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal Wall Wound			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Exposure To Product			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Overdose			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal Bite			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complications Of Transplanted Pancreas			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electric Shock			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	3 / 159 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	3 / 159 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Fracture			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb Injury			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Nausea			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis Fracture			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scapula Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Injury			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid Haemorrhage			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haematoma			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			

subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna Fracture			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Limb Fracture			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vth Nerve Injury			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Dehiscence			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	2 / 83 (2.41%)	1 / 82 (1.22%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	2 / 83 (2.41%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Valve Stenosis			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac Disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular Disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Stenosis			
subjects affected / exposed	2 / 83 (2.41%)	1 / 82 (1.22%)	3 / 159 (1.89%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Cardiomyopathy			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Ischaemia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Balance Disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Artery Stenosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal Tunnel Syndrome			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	3 / 159 (1.89%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	1 / 83 (1.20%)	2 / 82 (2.44%)	3 / 159 (1.89%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dizziness			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrapyramidal Disorder			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic Coma			
subjects affected / exposed	8 / 83 (9.64%)	5 / 82 (6.10%)	8 / 159 (5.03%)
occurrences causally related to treatment / all	6 / 26	1 / 6	4 / 13
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Hypoglycaemic Seizure			
subjects affected / exposed	3 / 83 (3.61%)	2 / 82 (2.44%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	1 / 5	2 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic Unconsciousness			
subjects affected / exposed	6 / 83 (7.23%)	2 / 82 (2.44%)	13 / 159 (8.18%)
occurrences causally related to treatment / all	1 / 17	1 / 2	5 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar Stroke			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss Of Consciousness			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve Compression			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Microcytic Anaemia			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pernicious Anaemia			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Meniere's Disease			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otosclerosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 83 (0.00%)	3 / 82 (3.66%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	3 / 83 (3.61%)	3 / 82 (3.66%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diabetic Retinopathy			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Aneurysm			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Haemorrhage			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Vein Occlusion			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous Haemorrhage			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Hernia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain			

subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 1	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Gastric Emptying			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	2 / 83 (2.41%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Prolapse			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-Abdominal Haematoma			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric Artery Thrombosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Cyst			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Prolapse			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	4 / 159 (2.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Mass			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus Ulcer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Foot			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hidradenitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Erosion			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Lesion			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Ulcer			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Irritation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Nephropathy			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End Stage Renal Disease			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incontinence			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	3 / 159 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Renal Impairment			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Bladder Polyp			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyroid Mass			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diastasis Recti Abdominis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			

subjects affected / exposed	0 / 83 (0.00%)	2 / 82 (2.44%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	1 / 83 (1.20%)	2 / 82 (2.44%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis Of Jaw			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain In Extremity			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periarthritis			
subjects affected / exposed	2 / 83 (2.41%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid Arthritis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Osteoarthritis			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial Cyst			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Disorder			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigger Finger			
subjects affected / exposed	3 / 83 (3.61%)	2 / 82 (2.44%)	5 / 159 (3.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal Wall Abscess			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	2 / 83 (2.41%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter Site Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Foot Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis Staphylococcal			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Norovirus			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Skin Ulcer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Abscess			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Site Infection			
subjects affected / exposed	12 / 83 (14.46%)	5 / 82 (6.10%)	5 / 159 (3.14%)
occurrences causally related to treatment / all	8 / 12	2 / 5	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelitis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	0 / 83 (0.00%)	2 / 82 (2.44%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	3 / 159 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Acetonaemia			
subjects affected / exposed	6 / 83 (7.23%)	9 / 82 (10.98%)	9 / 159 (5.66%)
occurrences causally related to treatment / all	5 / 8	8 / 10	9 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	5 / 83 (6.02%)	7 / 82 (8.54%)	10 / 159 (6.29%)
occurrences causally related to treatment / all	4 / 7	4 / 7	3 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	6 / 159 (3.77%)
occurrences causally related to treatment / all	0 / 1	1 / 2	6 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketosis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	9 / 83 (10.84%)	11 / 82 (13.41%)	19 / 159 (11.95%)
occurrences causally related to treatment / all	6 / 10	10 / 11	19 / 26
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	13 / 83 (15.66%)	3 / 82 (3.66%)	9 / 159 (5.66%)
occurrences causally related to treatment / all	3 / 13	1 / 3	7 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ketosis			
subjects affected / exposed	1 / 83 (1.20%)	3 / 82 (3.66%)	4 / 159 (2.52%)
occurrences causally related to treatment / all	0 / 1	2 / 5	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overweight			

subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight Fluctuation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Insuman phase		
Total subjects affected by serious adverse events			
subjects affected / exposed	101 / 148 (68.24%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder Cancer			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast Cancer			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast Neoplasm			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hodgkin's Disease Lymphocyte Depletion Type Stage Iii			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Intestinal Adenocarcinoma			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningioma			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic Gastric Cancer			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Prostate Cancer			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Cancer			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Adventitial Cystic Disease			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arterial Disorder			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arterial Insufficiency			

subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arterial Occlusive Disease				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arteritis				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism Venous				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intermittent Claudication				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Orthostatic Hypotension				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral Arterial Occlusive Disease				

subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral Artery Occlusion			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral Artery Stenosis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral Ischaemia			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phlebitis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Superior Vena Cava Stenosis			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Arterial Therapeutic Procedure			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast Prosthesis Implantation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Caesarean Section			

subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cataract Operation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystectomy			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary Angioplasty			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary Artery Bypass			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary Revascularisation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cyst Removal			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Finger Repair Operation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric Bypass			

subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hospitalisation				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hysterectomy				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Leg Amputation				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mammoplasty				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medical Device Change				
subjects affected / exposed	2 / 148 (1.35%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Medical Device Implantation				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medical Device Removal				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian Cystectomy				

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreas Transplant			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Percutaneous Coronary Intervention			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral Nerve Operation			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral Revascularisation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatic Operation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Sympathetic Nerve Ablation			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal Transplant			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal Operation			

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator Cuff Repair			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus Operation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stent Placement			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical Vascular Shunt			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon Operation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toe Amputation			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transplant			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Delivery			

subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Live Birth			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pre-Eclampsia			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy			
subjects affected / exposed	5 / 148 (3.38%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Unintended Pregnancy			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Catheter Site Pain			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest Pain			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
General Physical Health Deterioration			

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Generalised Oedema			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Granuloma			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Impaired Healing			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaise			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Medical Device Site Atrophy			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Medical Device Site Erosion			
subjects affected / exposed	3 / 148 (2.03%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Medical Device Site Erythema			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Medical Device Site Haemorrhage			

subjects affected / exposed	3 / 148 (2.03%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Medical Device Site Inflammation			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Medical Device Site Pain			
subjects affected / exposed	11 / 148 (7.43%)		
occurrences causally related to treatment / all	10 / 12		
deaths causally related to treatment / all	0 / 0		
Oedema			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Oedema Due To Cardiac Disease			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema Peripheral			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prolapse			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Sudden Death			

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Swelling			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Amyloidosis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaphylactic Shock			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drug Hypersensitivity			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Insulin Autoimmune Syndrome			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Breast Enlargement			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Genital Prolapse			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Haemorrhagic Ovarian Cyst				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Menometrorrhagia				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metrorrhagia				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian Cyst				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine Polyp				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acute Pulmonary Oedema				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic Obstructive Pulmonary Disease				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Dyspnoea			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dyspnoea Exertional			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epistaxis			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oropharyngeal Pain			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary Embolism			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Pulmonary Oedema			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sleep Apnoea Syndrome			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			

Depression			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Major Depression			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mania			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric Decompensation			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sleep Disorder			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicidal Ideation			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicide Attempt			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood Glucose Fluctuation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood Glucose Increased			

subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiovascular Evaluation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heart Rate Increased			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Laparoscopy			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Medical Observation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight Increased			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Abdominal Wall Wound			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental Exposure To Product			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental Overdose			

subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acetabulum Fracture				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Animal Bite				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ankle Fracture				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clavicle Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Complications Of Transplanted Pancreas				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electric Shock				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				

subjects affected / exposed	2 / 148 (1.35%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Femoral Neck Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur Fracture				
subjects affected / exposed	2 / 148 (1.35%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Foot Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint Dislocation				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ligament Sprain				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Limb Injury				

subjects affected / exposed	3 / 148 (2.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Lower Limb Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural Nausea				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pubis Fracture				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Road Traffic Accident				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Scapula Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scar				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Skin Injury				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Subarachnoid Haemorrhage				

subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural Haematoma				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thoracic Vertebral Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ulna Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper Limb Fracture				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vth Nerve Injury				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound Dehiscence				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Wrist Fracture				

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angina Pectoris			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic Valve Stenosis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial Fibrillation			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Cardiac Arrest			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac Disorder			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac Failure			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiovascular Disorder			

subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary Artery Disease			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary Artery Stenosis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ischaemic Cardiomyopathy			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial Infarction			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Myocardial Ischaemia			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Balance Disorder			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid Artery Stenosis			

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular Accident			
subjects affected / exposed	5 / 148 (3.38%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extrapyramidal Disorder			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemic Coma			
subjects affected / exposed	6 / 148 (4.05%)		
occurrences causally related to treatment / all	3 / 13		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemic Seizure			

subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemic Unconsciousness			
subjects affected / exposed	6 / 148 (4.05%)		
occurrences causally related to treatment / all	3 / 9		
deaths causally related to treatment / all	0 / 0		
Lacunar Stroke			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Loss Of Consciousness			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Migraine			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nerve Compression			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuralgia			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Paraesthesia			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sciatica			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient Ischaemic Attack			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Microcytic Anaemia			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pernicious Anaemia			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Meniere's Disease			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otosclerosis			

subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diabetic Retinopathy			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal Aneurysm			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal Detachment			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal Haemorrhage			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal Vein Occlusion			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitreous Haemorrhage			

subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal Hernia			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal Pain			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal Pain Upper			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhoidal Haemorrhage			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Impaired Gastric Emptying			

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal Hernia			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal Obstruction			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal Prolapse			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intra-Abdominal Haematoma			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mesenteric Artery Thrombosis			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	3 / 148 (2.03%)		
occurrences causally related to treatment / all	1 / 14		
deaths causally related to treatment / all	0 / 0		
Pancreatic Cyst			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal Prolapse			

subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Umbilical Hernia			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	9 / 148 (6.08%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic Mass			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Decubitus Ulcer			

subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Dermatitis			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic Foot			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eczema			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hidradenitis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin Erosion			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Skin Lesion			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin Ulcer			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute Kidney Injury			

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder Irritation			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic Nephropathy			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
End Stage Renal Disease			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incontinence			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal Colic			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Failure			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal Impairment			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary Bladder Polyp			

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary Incontinence			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Thyroid Mass			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arthropathy			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Back Pain			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bursitis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diastasis Recti Abdominis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Foot Deformity				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral Disc Disorder				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral Disc Protrusion				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lumbar Spinal Stenosis				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal Pain				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteitis				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis Of Jaw				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain In Extremity				

subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periarthritis				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rheumatoid Arthritis				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Osteoarthritis				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spondylolisthesis				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Synovial Cyst				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Synovitis				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon Disorder				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tenosynovitis				

subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Trigger Finger			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal Wall Abscess			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Anal Abscess			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Catheter Site Infection			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis			

subjects affected / exposed	2 / 148 (1.35%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Device Related Infection				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic Foot Infection				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocarditis Staphylococcal				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	5 / 148 (3.38%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis Norovirus				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis Viral				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes Zoster				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected Skin Ulcer				

subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	2 / 148 (1.35%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Laryngitis				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Localised Infection				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung Abscess				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medical Device Site Infection				
subjects affected / exposed	11 / 148 (7.43%)			
occurrences causally related to treatment / all	9 / 13			
deaths causally related to treatment / all	0 / 0			
Paronychia				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				

subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post Procedural Infection				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelitis				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory Tract Infection				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 148 (0.68%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	0 / 148 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Infection				
subjects affected / exposed	2 / 148 (1.35%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Urosepsis				

subjects affected / exposed	2 / 148 (1.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Viral Infection			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Acetonaemia			
subjects affected / exposed	5 / 148 (3.38%)		
occurrences causally related to treatment / all	3 / 7		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	18 / 148 (12.16%)		
occurrences causally related to treatment / all	18 / 25		
deaths causally related to treatment / all	0 / 0		
Diabetic Ketoacidosis			
subjects affected / exposed	5 / 148 (3.38%)		
occurrences causally related to treatment / all	3 / 6		
deaths causally related to treatment / all	0 / 0		
Diabetic Ketosis			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	20 / 148 (13.51%)		
occurrences causally related to treatment / all	24 / 30		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			

subjects affected / exposed	18 / 148 (12.16%)		
occurrences causally related to treatment / all	6 / 26		
deaths causally related to treatment / all	0 / 0		
Ketosis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Obesity			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Overweight			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight Fluctuation			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Insuman comparative phase	Insuplant comparative phase	Insuplant phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	74 / 83 (89.16%)	66 / 82 (80.49%)	130 / 159 (81.76%)
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 83 (4.82%)	5 / 82 (6.10%)	4 / 159 (2.52%)
occurrences (all)	4	5	4
Lymphocele			
subjects affected / exposed	0 / 83 (0.00%)	3 / 82 (3.66%)	8 / 159 (5.03%)
occurrences (all)	0	3	8
Surgical and medical procedures			

Cataract Operation subjects affected / exposed occurrences (all)	2 / 83 (2.41%) 3	7 / 82 (8.54%) 7	1 / 159 (0.63%) 1
Nervous system disorders Headache subjects affected / exposed occurrences (all)	6 / 83 (7.23%) 7	8 / 82 (9.76%) 11	10 / 159 (6.29%) 15
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	0 / 83 (0.00%) 0	0 / 82 (0.00%) 0	4 / 159 (2.52%) 4
Influenza Like Illness subjects affected / exposed occurrences (all)	4 / 83 (4.82%) 4	1 / 82 (1.22%) 1	5 / 159 (3.14%) 5
Medical Device Site Pain subjects affected / exposed occurrences (all)	1 / 83 (1.20%) 1	2 / 82 (2.44%) 2	7 / 159 (4.40%) 7
Oedema Peripheral subjects affected / exposed occurrences (all)	0 / 83 (0.00%) 0	5 / 82 (6.10%) 7	3 / 159 (1.89%) 4
Pyrexia subjects affected / exposed occurrences (all)	3 / 83 (3.61%) 3	0 / 82 (0.00%) 0	3 / 159 (1.89%) 3
Eye disorders Macular Oedema subjects affected / exposed occurrences (all)	5 / 83 (6.02%) 5	3 / 82 (3.66%) 5	3 / 159 (1.89%) 3
Gastrointestinal disorders Abdominal Pain subjects affected / exposed occurrences (all)	5 / 83 (6.02%) 6	3 / 82 (3.66%) 3	14 / 159 (8.81%) 17
Diarrhoea subjects affected / exposed occurrences (all)	3 / 83 (3.61%) 4	3 / 82 (3.66%) 4	8 / 159 (5.03%) 8
Gastrointestinal Disorder			

subjects affected / exposed occurrences (all)	4 / 83 (4.82%) 5	1 / 82 (1.22%) 1	8 / 159 (5.03%) 8
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	1 / 83 (1.20%) 1	4 / 82 (4.88%) 4	11 / 159 (6.92%) 12
Oropharyngeal Pain subjects affected / exposed occurrences (all)	4 / 83 (4.82%) 4	1 / 82 (1.22%) 1	8 / 159 (5.03%) 16
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	10 / 83 (12.05%) 10	2 / 82 (2.44%) 2	7 / 159 (4.40%) 7
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	11 / 83 (13.25%) 11	4 / 82 (4.88%) 4	8 / 159 (5.03%) 10
Back Pain subjects affected / exposed occurrences (all)	12 / 83 (14.46%) 19	7 / 82 (8.54%) 8	8 / 159 (5.03%) 11
Musculoskeletal Pain subjects affected / exposed occurrences (all)	5 / 83 (6.02%) 5	3 / 82 (3.66%) 3	8 / 159 (5.03%) 9
Pain In Extremity subjects affected / exposed occurrences (all)	6 / 83 (7.23%) 6	3 / 82 (3.66%) 3	11 / 159 (6.92%) 12
Tendonitis subjects affected / exposed occurrences (all)	8 / 83 (9.64%) 8	6 / 82 (7.32%) 6	9 / 159 (5.66%) 10
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	24 / 83 (28.92%) 36	20 / 82 (24.39%) 35	27 / 159 (16.98%) 38
Cystitis subjects affected / exposed occurrences (all)	4 / 83 (4.82%) 5	2 / 82 (2.44%) 5	14 / 159 (8.81%) 15

Ear Infection			
subjects affected / exposed	5 / 83 (6.02%)	3 / 82 (3.66%)	7 / 159 (4.40%)
occurrences (all)	5	3	9
Gastroenteritis			
subjects affected / exposed	10 / 83 (12.05%)	9 / 82 (10.98%)	15 / 159 (9.43%)
occurrences (all)	11	9	20
Influenza			
subjects affected / exposed	10 / 83 (12.05%)	9 / 82 (10.98%)	25 / 159 (15.72%)
occurrences (all)	10	11	32
Nasopharyngitis			
subjects affected / exposed	12 / 83 (14.46%)	9 / 82 (10.98%)	16 / 159 (10.06%)
occurrences (all)	16	9	17
Pharyngitis			
subjects affected / exposed	5 / 83 (6.02%)	3 / 82 (3.66%)	2 / 159 (1.26%)
occurrences (all)	6	3	3
Pneumonia			
subjects affected / exposed	2 / 83 (2.41%)	1 / 82 (1.22%)	2 / 159 (1.26%)
occurrences (all)	2	1	2
Rhinitis			
subjects affected / exposed	6 / 83 (7.23%)	3 / 82 (3.66%)	10 / 159 (6.29%)
occurrences (all)	7	4	14
Sinusitis			
subjects affected / exposed	8 / 83 (9.64%)	7 / 82 (8.54%)	7 / 159 (4.40%)
occurrences (all)	10	7	7
Tonsillitis			
subjects affected / exposed	6 / 83 (7.23%)	5 / 82 (6.10%)	5 / 159 (3.14%)
occurrences (all)	8	5	5
Tooth Abscess			
subjects affected / exposed	6 / 83 (7.23%)	2 / 82 (2.44%)	6 / 159 (3.77%)
occurrences (all)	6	3	7
Tooth Infection			
subjects affected / exposed	4 / 83 (4.82%)	3 / 82 (3.66%)	10 / 159 (6.29%)
occurrences (all)	5	4	12
Tracheitis			
subjects affected / exposed	7 / 83 (8.43%)	0 / 82 (0.00%)	5 / 159 (3.14%)
occurrences (all)	9	0	6

Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 83 (0.00%) 0	3 / 82 (3.66%) 3	8 / 159 (5.03%) 8
Urinary Tract Infection subjects affected / exposed occurrences (all)	14 / 83 (16.87%) 25	8 / 82 (9.76%) 16	18 / 159 (11.32%) 29
Metabolism and nutrition disorders			
Acetonaemia subjects affected / exposed occurrences (all)	7 / 83 (8.43%) 9	10 / 82 (12.20%) 14	8 / 159 (5.03%) 9
Diabetes Mellitus Inadequate Control subjects affected / exposed occurrences (all)	12 / 83 (14.46%) 12	13 / 82 (15.85%) 18	24 / 159 (15.09%) 28
Hyperglycaemia subjects affected / exposed occurrences (all)	18 / 83 (21.69%) 21	8 / 82 (9.76%) 10	30 / 159 (18.87%) 34
Ketosis subjects affected / exposed occurrences (all)	6 / 83 (7.23%) 8	0 / 82 (0.00%) 0	6 / 159 (3.77%) 7
Vitamin D Deficiency subjects affected / exposed occurrences (all)	2 / 83 (2.41%) 2	7 / 82 (8.54%) 7	5 / 159 (3.14%) 5

Non-serious adverse events	Insuman phase		
Total subjects affected by non-serious adverse events subjects affected / exposed	101 / 148 (68.24%)		
Vascular disorders			
Hypertension subjects affected / exposed occurrences (all)	9 / 148 (6.08%) 9		
Lymphocele subjects affected / exposed occurrences (all)	6 / 148 (4.05%) 7		
Surgical and medical procedures			
Cataract Operation subjects affected / exposed occurrences (all)	1 / 148 (0.68%) 1		

Nervous system disorders			
Headache			
subjects affected / exposed	9 / 148 (6.08%)		
occurrences (all)	11		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 148 (5.41%)		
occurrences (all)	8		
Influenza Like Illness			
subjects affected / exposed	11 / 148 (7.43%)		
occurrences (all)	14		
Medical Device Site Pain			
subjects affected / exposed	14 / 148 (9.46%)		
occurrences (all)	14		
Oedema Peripheral			
subjects affected / exposed	5 / 148 (3.38%)		
occurrences (all)	5		
Pyrexia			
subjects affected / exposed	8 / 148 (5.41%)		
occurrences (all)	9		
Eye disorders			
Macular Oedema			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	16 / 148 (10.81%)		
occurrences (all)	18		
Diarrhoea			
subjects affected / exposed	12 / 148 (8.11%)		
occurrences (all)	12		
Gastrointestinal Disorder			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	7 / 148 (4.73%) 10		
Oropharyngeal Pain subjects affected / exposed occurrences (all)	2 / 148 (1.35%) 2		
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	2 / 148 (1.35%) 2		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	5 / 148 (3.38%) 5		
Back Pain subjects affected / exposed occurrences (all)	9 / 148 (6.08%) 9		
Musculoskeletal Pain subjects affected / exposed occurrences (all)	4 / 148 (2.70%) 5		
Pain In Extremity subjects affected / exposed occurrences (all)	7 / 148 (4.73%) 8		
Tendonitis subjects affected / exposed occurrences (all)	5 / 148 (3.38%) 5		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	13 / 148 (8.78%) 15		
Cystitis subjects affected / exposed occurrences (all)	9 / 148 (6.08%) 13		
Ear Infection subjects affected / exposed occurrences (all)	3 / 148 (2.03%) 3		

Gastroenteritis			
subjects affected / exposed	10 / 148 (6.76%)		
occurrences (all)	12		
Influenza			
subjects affected / exposed	20 / 148 (13.51%)		
occurrences (all)	28		
Nasopharyngitis			
subjects affected / exposed	19 / 148 (12.84%)		
occurrences (all)	26		
Pharyngitis			
subjects affected / exposed	2 / 148 (1.35%)		
occurrences (all)	2		
Pneumonia			
subjects affected / exposed	8 / 148 (5.41%)		
occurrences (all)	9		
Rhinitis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	6 / 148 (4.05%)		
occurrences (all)	6		
Tonsillitis			
subjects affected / exposed	0 / 148 (0.00%)		
occurrences (all)	0		
Tooth Abscess			
subjects affected / exposed	3 / 148 (2.03%)		
occurrences (all)	5		
Tooth Infection			
subjects affected / exposed	5 / 148 (3.38%)		
occurrences (all)	6		
Tracheitis			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences (all)	1		
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 148 (0.68%)		
occurrences (all)	1		

Urinary Tract Infection subjects affected / exposed occurrences (all)	15 / 148 (10.14%) 21		
Metabolism and nutrition disorders			
Acetonaemia subjects affected / exposed occurrences (all)	4 / 148 (2.70%) 4		
Diabetes Mellitus Inadequate Control subjects affected / exposed occurrences (all)	15 / 148 (10.14%) 15		
Hyperglycaemia subjects affected / exposed occurrences (all)	15 / 148 (10.14%) 15		
Ketosis subjects affected / exposed occurrences (all)	2 / 148 (1.35%) 2		
Vitamin D Deficiency subjects affected / exposed occurrences (all)	4 / 148 (2.70%) 4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 March 2011	Following amendments were made: - To comply with the standard practice in the real life for the Insuplant non comparative phase: time to refill and blood withdrawal for HbA1c and anti-insulin antibodies were scheduled according to the site usual care. - Inclusion criteria for Insuman non comparative phase were added. Subjets who didn't participate to the comparative phase nor to the Insuplant non-comparative phase were allowed to participate directly to the Insuman non-comparative phase. - Correction of a mistake in the initial version of the protocol: no blood sample was collected for fasting plasma glucose, lipid profile (total cholesterol, high-density lipoprotein and low-density lipoprotein cholesterol, triglycerides) and chemistry (aspartate transferase, alanine transaminase, serum creatinine).
06 June 2011	- To allow the inclusion, in the Insuman non-comparative phase, of subjects not previously treated with Minimed implantable pump, but requiring CIPII therapy. - To allow subjects being pregnant during Insuman non-comparative phase to continue their treatment with Insuman Implantable 400 IU/mL as the duration of this phase was planned to end only when the product was marketed and as the safety profile of insulin is well established in pregnancy.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported