

Thorin Demo	Eligibility and Demographics	Subject Number <input style="width:80%;" type="text" value="99999"/>
		Subject Initials <input style="width:80%;" type="text" value="1"/>
SCREENING		Date of Screening <input style="width:80%;" type="text" value="28/12/1996"/> <small>Day Month Year</small>

Inclusion	Yes	No
1. Inclusion item 1?.....	<input type="text" value="A"/>	
2. Inclusion item 2?.....	<input type="text" value="B"/>	
3. Inclusion item 3?.....	<input type="text" value="C"/>	
Date signed <input style="width:150px;" type="text" value="25/09/1987"/> <small>Day Month Year</small>		
4. Is the subject ≥ 18 years of age?.....	<input type="text" value="D"/>	
Date of birth <input style="width:150px;" type="text" value="26/10/1988"/> <small>Day Month Year</small>		
5. Is the subject willing to comply with all aspects of the treatment and evaluation schedule?	<input type="text" value="E"/>	
6. Inclusion, item 6?.....	<input type="text" value="F"/>	NA
7. If female subject and of childbearing potential, is the pregnancy test negative?.....	<input type="text" value="R"/>	
Date of pregnancy test <input style="width:150px;" type="text" value="27/11/1989"/> <small>Day Month Year</small>		
8. Inclusionr item 8?.....	<input type="text" value="G"/>	
Exclusion	Yes	No
9. Is the subject a participant in another clinical research study which the Investigator believes may interfere with the purpose of this study?.....	<input type="text" value="H"/>	
10. Exclusion item 10?.....	<input type="text" value="J"/>	
11. Exclusion item 11?.....	<input type="text" value="K"/>	
12. Exclusion item 12?.....	<input type="text" value="L"/>	
13. Exclusion item 13?.....	<input type="text" value="M"/>	
14. Exclusion item 10?.....	<input type="text" value="N"/>	
15. Exclusion item 15?.....	<input type="text" value="P"/>	
16. Exclusion item 16?.....	<input type="text" value="Q"/>	

SCREENING	Eligibility, Demographics and Physical Examination	Subject Number <input type="text" value="99999"/>
		Subject Initials <input type="text" value="1"/>

Eligibility criteria discussed

If the subject does not meet all eligibility criteria, but requests to be enrolled in the study, please contact Thorin

Eligibility criterium #	Discussed with and subject enrollment authorized by:	Discussion date:
<input type="text" value="13"/>	<input type="text" value="EDDESC1"/>	<input type="text" value="25/09/1987"/>
		Day Month Year
<input type="text" value="14"/>	<input type="text" value="EDDESC2"/>	<input type="text" value="26/10/1988"/>
		Day Month Year

Demographics

Gender: Male
 Female

Physical Examination

From the subject's pre-study medical history and physical exam, answer the following questions. Use Comments Form for any written comments.

- Does the subject smoke? Stopped; quit date:
Month Year
- Does the subject have a known disease? No
 If YES, describe:
- Does the subject have hypertension? No
 If YES, are medications taken for hypertension? No
- Does subject have hypercholesterolemia? No
 If YES, are medications taken for hypercholesterolemia? No
- Does subject have diabetes? No
 If YES, check type: NIDDM
- Does subject have a history of events? No
 If YES, check type: Other:

SCREENING	Medical History and Medication	Subject Number <input style="width: 100px;" type="text" value="99999"/>
		Subject Initials <input style="width: 50px;" type="text" value="1"/>

Medical History

7. Does the subject have medical history affecting vascular system or coagulation? No
 If YES, please list below

Diagnosis	Date of Diagnosis	Active
<input style="width: 100%;" type="text" value="MHTERM1"/>	<input style="width: 100%;" type="text" value="18/02/1980"/> <small>Month Year</small>	<input type="text" value="A"/> No
<input style="width: 100%;" type="text" value="MHTERM2"/>	<input style="width: 100%;" type="text" value="19/03/1981"/> <small>Month Year</small>	<input type="text" value="B"/> No
<input style="width: 100%;" type="text" value="MHTERM3"/>	<input style="width: 100%;" type="text" value="20/04/1982"/> <small>Month Year</small>	<input type="text" value="C"/> No
<input style="width: 100%;" type="text" value="MHTERM4"/>	<input style="width: 100%;" type="text" value="21/05/1983"/> <small>Month Year</small>	<input type="text" value="D"/> No
<input style="width: 100%;" type="text" value="MHTERM5"/>	<input style="width: 100%;" type="text" value="22/06/1984"/> <small>Month Year</small>	<input type="text" value="E"/> No

Prior surgeries/procedures

8. Does the subject have prior surgeries/procedures? No
 If YES, please list below

Surgery/Procedure	Indication	Date of Surgery
<input style="width: 100%;" type="text" value="MHTERM6"/>	<input style="width: 100%;" type="text" value="MHDESC1"/>	<input style="width: 100%;" type="text" value="23/07/1985"/> <small>Month Year</small>
<input style="width: 100%;" type="text" value="MHTERM7"/>	<input style="width: 100%;" type="text" value="MHDESC2"/>	<input style="width: 100%;" type="text" value="24/08/1986"/> <small>Month Year</small>
<input style="width: 100%;" type="text" value="MHTERM8"/>	<input style="width: 100%;" type="text" value="MHDESC3"/>	<input style="width: 100%;" type="text" value="25/09/1987"/> <small>Month Year</small>
<input style="width: 100%;" type="text" value="MHTERM9"/>	<input style="width: 100%;" type="text" value="MHDESC4"/>	<input style="width: 100%;" type="text" value="26/10/1988"/> <small>Month Year</small>
<input style="width: 100%;" type="text" value="MHTERM10"/>	<input style="width: 100%;" type="text" value="MHDESC5"/>	<input style="width: 100%;" type="text" value="27/11/1989"/> <small>Month Year</small>

Medication

9. Did the subject take any medication within 1 week prior to surgery that may affect outcome? No

If YES, indicate which apply:

- | | |
|---|---|
| <input type="text" value="J"/> Medication 1 | <input type="text" value="N"/> Medication 5 |
| <input type="text" value="K"/> Medication 2 | <input type="text" value="P"/> Medication 6 |
| <input type="text" value="L"/> Medication 3 | <input type="text" value="Q"/> Medication 7 |
| <input type="text" value="M"/> Medication 4 | |

List all current Concomitant Medications (generic name) on the Concomitant Medication Form

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Plate # 040

Visit #

		Subject Number <input type="text" value="99999"/>
		Subject Initials <input type="text" value="1"/>

Laboratory Measurements

List only when parameter is 'out of range' OR parameter is 'not done'

Date sample taken for Hematology:
Day Month Year

Date sample taken for Biochemistry:
Day Month Year

Parameter	Check if Not done	Result	Unit	Out of range		Clinically significant		Comment
				Yes	No	Yes	No	
WBC	<input type="checkbox" value="A"/>	001.01	LBORRESU1	<input checked="" type="checkbox" value="X"/>	<input type="checkbox"/>	<input type="checkbox" value="U"/>	<input type="checkbox"/>	LBREAS1
Differential WBC	<input type="checkbox" value="B"/>	001.02	LBORRESU2	<input type="checkbox" value="Y"/>	<input type="checkbox"/>	<input type="checkbox" value="V"/>	<input type="checkbox"/>	LBREAS2
RBC	<input type="checkbox" value="C"/>	001.03	LBORRESU3	<input type="checkbox" value="Z"/>	<input type="checkbox"/>	<input type="checkbox" value="W"/>	<input type="checkbox"/>	LBREAS3
RDW	<input type="checkbox" value="D"/>	001.04	LBORRESU4	<input type="checkbox" value="A"/>	<input type="checkbox"/>	<input type="checkbox" value="X"/>	<input type="checkbox"/>	LBREAS4
Hemoglobin	<input type="checkbox" value="E"/>	001.05	LBORRESU5	<input type="checkbox" value="B"/>	<input type="checkbox"/>	<input type="checkbox" value="Y"/>	<input type="checkbox"/>	LBREAS5
Hematocrit	<input type="checkbox" value="F"/>	001.06	LBORRESU6	<input type="checkbox" value="C"/>	<input type="checkbox"/>	<input type="checkbox" value="Z"/>	<input type="checkbox"/>	LBREAS6
MCH	<input type="checkbox" value="G"/>	001.07	LBORRESU7	<input type="checkbox" value="D"/>	<input type="checkbox"/>	<input type="checkbox" value="A"/>	<input type="checkbox"/>	LBREAS7
MCHC	<input type="checkbox" value="H"/>	001.08	LBORRESU8	<input type="checkbox" value="E"/>	<input type="checkbox"/>	<input type="checkbox" value="B"/>	<input type="checkbox"/>	LBREAS8
MCV	<input type="checkbox" value="J"/>	001.09	LBORRESU9	<input type="checkbox" value="F"/>	<input type="checkbox"/>	<input type="checkbox" value="C"/>	<input type="checkbox"/>	LBREAS9
Platelet Count	<input type="checkbox" value="K"/>	001.11	LBORRESU10	<input type="checkbox" value="G"/>	<input type="checkbox"/>	<input type="checkbox" value="D"/>	<input type="checkbox"/>	LBREAS10
Total bilirubin	<input type="checkbox" value="L"/>	001.12	LBORRESU11	<input type="checkbox" value="H"/>	<input type="checkbox"/>	<input type="checkbox" value="E"/>	<input type="checkbox"/>	LBREAS11
Random glucose	<input type="checkbox" value="M"/>	001.13	LBORRESU12	<input type="checkbox" value="J"/>	<input type="checkbox"/>	<input type="checkbox" value="F"/>	<input type="checkbox"/>	LBREAS12
Serum creatinine	<input type="checkbox" value="N"/>	001.14	LBORRESU13	<input type="checkbox" value="K"/>	<input type="checkbox"/>	<input type="checkbox" value="G"/>	<input type="checkbox"/>	LBREAS13
AST	<input type="checkbox" value="P"/>	001.15	LBORRESU14	<input type="checkbox" value="L"/>	<input type="checkbox"/>	<input type="checkbox" value="H"/>	<input type="checkbox"/>	LBREAS14
Alkaline Phosphatase	<input type="checkbox" value="Q"/>	001.16	LBORRESU15	<input type="checkbox" value="M"/>	<input type="checkbox"/>	<input type="checkbox" value="J"/>	<input type="checkbox"/>	LBREAS15
ALT	<input type="checkbox" value="R"/>	001.17	LBORRESU16	<input type="checkbox" value="N"/>	<input type="checkbox"/>	<input type="checkbox" value="K"/>	<input type="checkbox"/>	LBREAS16
Blood urea nitrogen	<input type="checkbox" value="S"/>	001.18	LBORRESU17	<input type="checkbox" value="P"/>	<input type="checkbox"/>	<input type="checkbox" value="L"/>	<input type="checkbox"/>	LBREAS17
Sodium	<input type="checkbox" value="T"/>	001.19	LBORRESU18	<input type="checkbox" value="Q"/>	<input type="checkbox"/>	<input type="checkbox" value="M"/>	<input type="checkbox"/>	LBREAS18
Potassium	<input type="checkbox" value="U"/>	001.21	LBORRESU19	<input type="checkbox" value="R"/>	<input type="checkbox"/>	<input type="checkbox" value="N"/>	<input type="checkbox"/>	LBREAS19
Chloride	<input type="checkbox" value="V"/>	001.22	LBORRESU20	<input type="checkbox" value="S"/>	<input type="checkbox"/>	<input type="checkbox" value="P"/>	<input type="checkbox"/>	LBREAS20
Hb-A1c	<input type="checkbox" value="W"/>	001.23	LBORRESU21	<input type="checkbox" value="T"/>	<input type="checkbox"/>	<input type="checkbox" value="Q"/>	<input type="checkbox"/>	LBREAS21

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Plate # 040

Visit #

		Subject Number <input type="text" value="99999"/>
		Subject Initials <input type="text" value="1"/>

Laboratory Measurements

List only when parameter is 'out of range' OR parameter is 'not done'

Date sample taken for Hematology:
Day Month Year

Date sample taken for Biochemistry:
Day Month Year

Parameter	Check if Not done	Result	Unit	Out of range		Clinically significant		Comment
				Yes	No	Yes	No	
WBC	<input type="checkbox" value="A"/>	001.01	LBORRESU1	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS1
Differential WBC	<input type="checkbox" value="B"/>	001.02	LBORRESU2	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS2
RBC	<input type="checkbox" value="C"/>	001.03	LBORRESU3	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS3
RDW	<input type="checkbox" value="D"/>	001.04	LBORRESU4	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS4
Hemoglobin	<input type="checkbox" value="E"/>	001.05	LBORRESU5	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS5
Hematocrit	<input type="checkbox" value="F"/>	001.06	LBORRESU6	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS6
MCH	<input type="checkbox" value="G"/>	001.07	LBORRESU7	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS7
MCHC	<input type="checkbox" value="H"/>	001.08	LBORRESU8	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS8
MCV	<input type="checkbox" value="I"/>	001.09	LBORRESU9	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS9
Platelet Count	<input type="checkbox" value="K"/>	001.11	LBORRESU10	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS10
Total bilirubin	<input type="checkbox" value="L"/>	001.12	LBORRESU11	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS11
Random glucose	<input type="checkbox" value="M"/>	001.13	LBORRESU12	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS12
Serum creatinine	<input type="checkbox" value="N"/>	001.14	LBORRESU13	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS13
AST	<input type="checkbox" value="P"/>	001.15	LBORRESU14	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS14
Alkaline Phosphatase	<input type="checkbox" value="Q"/>	001.16	LBORRESU15	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS15
ALT	<input type="checkbox" value="R"/>	001.17	LBORRESU16	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS16
Blood urea nitrogen	<input type="checkbox" value="S"/>	001.18	LBORRESU17	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS17
Sodium	<input type="checkbox" value="T"/>	001.19	LBORRESU18	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS18
Potassium	<input type="checkbox" value="U"/>	001.21	LBORRESU19	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS19
Chloride	<input type="checkbox" value="V"/>	001.22	LBORRESU20	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS20
Hb-A1c	<input type="checkbox" value="W"/>	001.23	LBORRESU21	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LBREAS21

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Plate # 046

Visit #

		Subject Number <input type="text" value="99999"/>
		Subject Initials <input type="text" value="1"/>

Laboratory Measurements (continued)

Parameter	Check if Not done	Result	Unit	Out of range		Clinically significant		Comment
				Yes	No	Yes	No	
Eosinophils	<input type="checkbox" value="A"/>	<input type="text" value="001.01"/>	<input type="text" value="LBORRESU1"/>	<input type="checkbox" value="F"/>	<input type="checkbox"/>	<input type="checkbox" value="L"/>	<input type="checkbox"/>	<input type="text" value="LBREAS1"/>
Basophils	<input type="checkbox" value="B"/>	<input type="text" value="001.02"/>	<input type="text" value="LBORRESU2"/>	<input type="checkbox" value="G"/>	<input type="checkbox"/>	<input type="checkbox" value="M"/>	<input type="checkbox"/>	<input type="text" value="LBREAS2"/>
Neutrophils	<input type="checkbox" value="C"/>	<input type="text" value="001.03"/>	<input type="text" value="LBORRESU3"/>	<input type="checkbox" value="H"/>	<input type="checkbox"/>	<input type="checkbox" value="N"/>	<input type="checkbox"/>	<input type="text" value="LBREAS3"/>
Monocytes	<input type="checkbox" value="D"/>	<input type="text" value="001.04"/>	<input type="text" value="LBORRESU4"/>	<input type="checkbox" value="J"/>	<input type="checkbox"/>	<input type="checkbox" value="P"/>	<input type="checkbox"/>	<input type="text" value="LBREAS4"/>
Lymphocytes	<input type="checkbox" value="E"/>	<input type="text" value="001.05"/>	<input type="text" value="LBORRESU5"/>	<input type="checkbox" value="K"/>	<input type="checkbox"/>	<input type="checkbox" value="Q"/>	<input type="checkbox"/>	<input type="text" value="LBREAS5"/>

DataFax #220

Plate # 046

Visit #

Subject Number

Subject Initials

Laboratory Measurements (continued)

Parameter	Check if Not done	Result	Unit	Out of range		Clinically significant		Comment
				Yes	No	Yes	No	
Eosinophils	<input type="checkbox" value="A"/>	<input type="text" value="001.01"/>	<input type="text" value="LBORRESU1"/>	<input type="checkbox" value="F"/>	<input type="checkbox"/>	<input type="checkbox" value="L"/>	<input type="checkbox"/>	<input type="text" value="LBREAS1"/>
Basophils	<input type="checkbox" value="B"/>	<input type="text" value="001.02"/>	<input type="text" value="LBORRESU2"/>	<input type="checkbox" value="G"/>	<input type="checkbox"/>	<input type="checkbox" value="M"/>	<input type="checkbox"/>	<input type="text" value="LBREAS2"/>
Neutrophils	<input type="checkbox" value="C"/>	<input type="text" value="001.03"/>	<input type="text" value="LBORRESU3"/>	<input type="checkbox" value="H"/>	<input type="checkbox"/>	<input type="checkbox" value="N"/>	<input type="checkbox"/>	<input type="text" value="LBREAS3"/>
Monocytes	<input type="checkbox" value="D"/>	<input type="text" value="001.04"/>	<input type="text" value="LBORRESU4"/>	<input type="checkbox" value="J"/>	<input type="checkbox"/>	<input type="checkbox" value="P"/>	<input type="checkbox"/>	<input type="text" value="LBREAS4"/>
Lymphocytes	<input type="checkbox" value="E"/>	<input type="text" value="001.05"/>	<input type="text" value="LBORRESU5"/>	<input type="checkbox" value="K"/>	<input type="checkbox"/>	<input type="checkbox" value="Q"/>	<input type="checkbox"/>	<input type="text" value="LBREAS5"/>

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Plate # 050

Visit #

SCREENING

**Baseline Measurements /
Investigator Sign-off**

Subject Number

Subject Initials

Duplex Doppler Flow

Is a Duplex Doppler Flow taken?

A No

If **YES**, please note the diameter and describe the results below:

mm. **Results**

Date Duplex Doppler Flow

Day Month Year

Angiography

Is an Angiography taken?

B No

If **YES**, please note the diameter and describe the results below:

mm. **Results**

Date Angiography

Day Month Year

Investigator Sign-off

I have personally reviewed all data recorded at **Screening** for completeness and accuracy.

Investigator's Signature: _____ C Date of Signature:
Day Month Year

OPERATIVE DAY

Treatment Record

Subject Number **99999**

Subject Initials **1**

Date of Surgery **28/12/1999**
Day Month Year

1. Surgery start time: Hours : Minutes
(first cut)

Time surgery ends: Hours : Minutes
(last stitch)

2. Name and location of sites:

EXLOC

3. Diameter mm. Type: Catalog number:

4a. Does the subject require assistance? No
if YES, stop enrollment into this study !

4b. Is complete surgery achieved ? No
if NO, stop enrollment into this study !

5. Time surgery finished: Hours : Minutes

6. Is the patient allocated to the treatment Group? No
If YES, time randomised: Hours : Minutes Number:

Affix randomization label to each copy of this treatment form:

7. Medication 1 used? No Units
If YES, total d

8. Medication 2 used? No Units
If YES, total d

9. Is an Angiography in 2 taken ? No
If YES, please note the diameter and describe the results:
 mm.

10. Were any other procedures applied / measurements conducted during surgery? No
If YES, please specify and note the results:

11. Is a digital image taken? No

Record all Adverse Events on the Adverse Events Form

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Plate # 070

Visit #

OPERATIVE DAY

Performance

Subject Number

Subject Initials

Please document all items immediately after operation!

Surgery Ratings

If this subject was treated, please rate the following items of performance

Excellent Good Fair Poor

1. item 1

2. item 2

3. item 3

4. item 4

Operating Room Comments

Please note ANY comments, positive or negative, by surgeon or Operating Room staff. Indicate the role of the person who made the comments.

Role

Comments

Investigator Sign-off

I have personally reviewed all data recorded at **Operative Day** for completeness and accuracy.

Investigator's Signature: Date of Signature:
Day Month Year

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Plate # 080

Visit #

Hospital Discharge

Post Operative Follow-up

Subject Number

Subject Initials

Date of Visit
Day Month Year

Post operative experience

1. Was surgery used at the treatment site: No
If YES, date of surgery:
Day Month Year
Total volume mL.

2. Did the subject return to surgery: No
If YES, surgical procedure performed:
Date of above procedure:
Day Month Year

Complete Adverse Event Form and fax to Thorin

3. Date Duplex Doppler Flow:
Day Month Year
Please note the diameter and describe the results:
Diameter mm. Results

List changes in medication on Concomitant Medication Form

4. Did any of the following complications occur at the operative site?
Infection No
Infection No
Infection No
Other No If YES, specify:

If any YES, Record all Adverse Events on the Adverse Event Form

Investigator Sign-off

I have personally reviewed all data recorded for this **Visit** for completeness and accuracy.

Investigator's Signature: Date of Signature:
Day Month Year

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Plate # 090

Visit #

Follow-up	Subject Number <input type="text" value="99999"/>
	Subject Initials <input type="text" value="1"/>
Date of Follow-up visit <input type="text" value="28/12/1990"/>	
<small>Day Month Year</small>	

Adverse Events and Concomitant Medication Changes

1. Did the subject develop any adverse events during the post-discharge period? No

Record any Adverse Events the subject experienced after the previous visit on the Adverse Event Form.

List all changes in medication on the Concomitant Medication Form.

2. Is the subject taking prescribed medications as directed? No

If NO, please explain:

Duplex Doppler Flow

Is a Duplex Doppler Flow taken for this visit? No

If YES, please note the diameter and describe the results below:

mm. **Results**

Date Duplex Doppler Flow

Day Month Year

Angiography

Is an Angiography taken since last visit? No

If YES, please note the diameter and describe the results below:

mm. **Results**

Date Angiography

Day Month Year

Investigator Sign-off

I have personally reviewed all data recorded for this **Follow-up Visit** for completeness and accuracy.

Investigator's Signature: _____ Date of Signature:
Day Month Year

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Plate # 100

Visit # 400

Study Termination

Subject Number 99999

Subject Initials 1

Date of Study Completion/Termination 28/12/1994
Day Month Year

Study Completion / Termination

1. Did the subject complete all study visits to date? B No

If **NO**, please check the one most appropriate reason below:

a. Protocol violation, please explain: STPVDESC

b. Lost to follow-up after 3 attempts to contact. Please provide dates for each of these 3 attempts:

1st telephone contact, date: 24/08/1986
Day Month Year

2nd telephone contact, date: 25/09/1987
Day Month Year

3rd contact by certified mail, dated: 26/10/1988
Day Month Year

Certified mail #: STCTDESC

c. Adverse Event, # 13

d. Death Date of Death: 27/11/1989
Day Month Year

Any death must be reported within 24 hours of the Investigator's first knowledge of it.

Complete SAE Form and fax within 24 hours of death to Thorin

e. Other, please explain: STOTHC

Investigator Sign-off

I have personally reviewed all data recorded for this **Termination Visit** and for **Concomitant Medication** for completeness and accuracy.

Investigator's Signature: _____ Date of Signature: 23/07/1985
Day Month Year

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Plate # 200

Visit # 200

Adverse Event	Subject Number 99999
	Subject Initials 1

Adverse Events

Adverse Event no. **13**

Description of Event **AETERM**

Startdate **23/07/1985**
Day Month Year

Ongoing at Study end

B Yes
No

Stopdate **24/08/1986**
Day Month Year

Severity (maximum)?

C Mild
Moderate
Severe

Pattern?

D Once
Continuous
Intermittent

Action taken?

E None
Medication → *Update the Concomitant Medication section.*
Surgery
Other → *Please describe at Details of AE*

Was Event related to Treatment?

F Definitely
Likely
Unlikely
Definitely not

Serious Adverse Event?

G Yes
No

Outcome?

H Recovered
Recovering
Recovered with sequelae
Not recovered
Death
Unknown

Details of Adverse Event:

AECOM

Investigator Sign-off

I have personally reviewed all data recorded for this **Adverse Event** for completeness and accuracy.

Investigator's Signature: _____ **A** Date of Signature: **22/06/1984**
Day Month Year

Adverse Event	Subject Number 99999
	Subject Initials 1

Adverse Events

Adverse Event no. **13**

Description of Event **AETERM**

Startdate **23/07/1985**
Day Month Year

Ongoing at Study end

B Yes
No

Stopdate **24/08/1986**
Day Month Year

Severity (maximum)?

C Mild
Moderate
Severe

Pattern?

D Once
Continuous
Intermittent

Action taken?

E None
Medication → *Update the Concomitant Medication section.*
Surgery
Other → *Please describe at Details of AE*

Was Event related to Treatment?

F Definitely
Likely
Unlikely
Definitely not

Serious Adverse Event?

G Yes
No

Outcome?

H Recovered
Recovering
Recovered with sequelae
Not recovered
Death
Unknown

Details of Adverse Event:

AECOM

Investigator Sign-off

I have personally reviewed all data recorded for this **Adverse Event** for completeness and accuracy.

Investigator's Signature: _____ **A** Date of Signature: **22/06/1984**
Day Month Year

Adverse Event	Subject Number 99999
	Subject Initials 1

Adverse Events

Adverse Event no. **13**

Description of Event **AETERM**

Startdate **23/07/1985**
Day Month Year

Ongoing at Study end

B Yes
No

Stopdate **24/08/1986**
Day Month Year

Severity (maximum)?

C Mild
Moderate
Severe

Pattern?

D Once
Continuous
Intermittent

Action taken?

E None
Medication → *Update the Concomitant Medication section.*
Surgery
Other → *Please describe at Details of AE*

Was Event related to Treatment?

F Definitely
Likely
Unlikely
Definitely not

Serious Adverse Event?

G Yes
No

Outcome?

H Recovered
Recovering
Recovered with sequelae
Not recovered
Death
Unknown

Details of Adverse Event:

AECOM

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Day Month Year

Adverse Event	Subject Number 99999
	Subject Initials 1

Adverse Events

Adverse Event no. **13**

Description of Event **AETERM**

Startdate **23/07/1985**
Day Month Year

Ongoing at Study end

B Yes
No

Stopdate **24/08/1986**
Day Month Year

Severity (maximum)?

C Mild
Moderate
Severe

Pattern?

D Once
Continuous
Intermittent

Action taken?

E None
Medication → *Update the Concomitant Medication section.*
Surgery
Other → *Please describe at Details of AE*

Was Event related to Treatment?

F Definitely
Likely
Unlikely
Definitely not

Serious Adverse Event?

G Yes
No

Outcome?

H Recovered
Recovering
Recovered with sequelae
Not recovered
Death
Unknown

Details of Adverse Event:

AECOM

Investigator Sign-off

I have personally reviewed all data recorded for this **Adverse Event** for completeness and accuracy.

Investigator's Signature: _____ **A** Date of Signature: **22/06/1984**
Day Month Year

DataFax #220

Plate # 210

Visit # 240

Serious Adverse Event

Subject Number 99999

Subject Initials 1

1. Adverse Event no. 13

Date SAE reported: 23/07/1985
Day Month Year

Clinical presentation of the Event

AESDESC

2. Why was the Adverse Event serious? (check only one, the primary reason for seriousness)

- B Resulted in Death —————> Was an autopsy preformed? H No
- C Is life-threatening
- D Requires in patient hospitalisation or prolongation of existing hospitalisation
- E Results in persistent or significant disability/incapacity
- F Is a congenital anomaly/birth defect
- G Other medically important condition

3. Relevant medical history and/or current medical condition:

AESMHIS

4. Concomitant medication or surgical procedures at the time the event started:

AESMED

5. Relevant Laboratory data:

AESLAB

6. Treatment of the event:

AESTRT

7. Outcome of the event:

AESOUT

Investigator Sign-off

I have personally reviewed all data recorded for this **Serious Adverse Event** for completeness and accuracy.

Investigator's Signature: _____ A Date of Signature: 22/06/1984
Day Month Year

DataFax #220

Plate # 210

Visit #

Serious Adverse Event

Subject Number

Subject Initials

1. Adverse Event no.

Date SAE reported:
Day Month Year

Clinical presentation of the Event

2. Why was the Adverse Event serious? (check only one, the primary reason for seriousness)

- B Resulted in Death Was an autopsy preformed? H No
- C Is life-threatening
- D Requires in patient hospitalisation or prolongation of existing hospitalisation
- E Results in persistent or significant disability/incapacity
- F Is a congenital anomaly/birth defect
- G Other medically important condition

3. Relevant medical history and/or current medical condition:

4. Concomitant medication or surgical procedures at the time the event started:

5. Relevant Laboratory data:

6. Treatment of the event:

7. Outcome of the event:

Investigator Sign-off

I have personally reviewed all data recorded for this **Serious Adverse Event** for completeness and accuracy.

Investigator's Signature: Date of Signature:
Day Month Year

Serious Adverse Event

Subject Number 99999

Subject Initials 1

1. Adverse Event no. 13

Date SAE reported: 23/07/1985 (Day Month Year)

Clinical presentation of the Event

AESDESC

2. Why was the Adverse Event serious? (check only one, the primary reason for seriousness)

- B Resulted in Death -> Was an autopsy preformed? H No
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AESMED

5. Relevant Laboratory data:

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6. Treatment of the event:

AESTRT

7. Outcome of the event:

AESOUT

Investigator Sign-off

I have personally reviewed all data recorded for this Serious Adverse Event for completeness and accuracy.

Investigator's Signature: A Date of Signature: 22/06/1984 (Day Month Year)

Serious Adverse Event

Subject Number 99999

Subject Initials 1

1. Adverse Event no. 13

Date SAE reported: 23/07/1985
Day Month Year

Clinical presentation of the Event

AESDESC

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3. Relevant medical history and/or current medical condition:

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4. Concomitant medication or surgical procedures at the time the event started:

AESMED

5. Relevant Laboratory data:

AESLAB

6. Treatment of the event:

AESTRT

7. Outcome of the event:

AESOUT

Investigator Sign-off

I have personally reviewed all data recorded for this **Serious Adverse Event** for completeness and accuracy.

Investigator's Signature: _____ A Date of Signature: 22/06/1984
Day Month Year

DataFax #220

Plate # 250

Visit # 250

Concomitant Medication

Subject Number 99999

Subject Initials 6

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT1 DOSTOT1 DOSU1 ROUTE1C1A AE, specify AE# 13
 Other: RSOTH1

Start date 18/02/1980 Stop date 23/07/1985 Ongoing at Study End
 Day Month Year Day Month Year F No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT2 DOSTOT2 DOSU2 ROUTE2DEB AE, specify AE# 14
 Other: RSOTH2

Start date 19/03/1981 Stop date 24/08/1986 Ongoing at Study End
 Day Month Year Day Month Year G No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT3 DOSTOT3 DOSU3 ROUTE3EDC AE, specify AE# 15
 Other: RSOTH3

Start date 20/04/1982 Stop date 25/09/1987 Ongoing at Study End
 Day Month Year Day Month Year H No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT4 DOSTOT4 DOSU4 ROUTE4IA D AE, specify AE# 16
 Other: RSOTH4

Start date 21/05/1983 Stop date 26/10/1988 Ongoing at Study End
 Day Month Year Day Month Year J No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT5 DOSTOT5 DOSU5 ROUTE5IB E AE, specify AE# 17
 Other: RSOTH5

Start date 22/06/1984 Stop date 27/11/1989 Ongoing at Study End
 Day Month Year Day Month Year K No

DataFax #220

Plate # 250

Visit # 251

Concomitant Medication

Subject Number 99999

Subject Initials 6

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT1 DOSTOT1 DOSU1 ROUTE1C1A AE, specify AE# 13
 Other: RSOTH1

Start date 18/02/1980 Stop date 23/07/1985 Ongoing at Study End F No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT2 DOSTOT2 DOSU2 ROUTE2DEB AE, specify AE# 14
 Other: RSOTH2

Start date 19/03/1981 Stop date 24/08/1986 Ongoing at Study End G No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT3 DOSTOT3 DOSU3 ROUTE3EDC AE, specify AE# 15
 Other: RSOTH3

Start date 20/04/1982 Stop date 25/09/1987 Ongoing at Study End H No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT4 DOSTOT4 DOSU4 ROUTE4IA D AE, specify AE# 16
 Other: RSOTH4

Start date 21/05/1983 Stop date 26/10/1988 Ongoing at Study End J No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT5 DOSTOT5 DOSU5 ROUTE5IB E AE, specify AE# 17
 Other: RSOTH5

Start date 22/06/1984 Stop date 27/11/1989 Ongoing at Study End K No

Concomitant Medication

Subject Number 99999
Subject Initials 6

Medication (generic name) TRT1 Total dose (24 hours) DOSTOT1 Units DOSU1 Route ROUTE1C Reason for use AE, specify AE# 13 Other: RSOTH1
Start date 18/02/1980 Stop date 23/07/1985 Ongoing at Study End F No

Medication (generic name) TRT2 Total dose (24 hours) DOSTOT2 Units DOSU2 Route ROUTE2DE Reason for use AE, specify AE# 14 Other: RSOTH2
Start date 19/03/1981 Stop date 24/08/1986 Ongoing at Study End G No

Medication (generic name) TRT3 Total dose (24 hours) DOSTOT3 Units DOSU3 Route ROUTE3ED Reason for use AE, specify AE# 15 Other: RSOTH3
Start date 20/04/1982 Stop date 25/09/1987 Ongoing at Study End H No

Medication (generic name) TRT4 Total dose (24 hours) DOSTOT4 Units DOSU4 Route ROUTE4IA Reason for use AE, specify AE# 16 Other: RSOTH4
Start date 21/05/1983 Stop date 26/10/1988 Ongoing at Study End J No

Medication (generic name) TRT5 Total dose (24 hours) DOSTOT5 Units DOSU5 Route ROUTE5IB Reason for use AE, specify AE# 17 Other: RSOTH5
Start date 22/06/1984 Stop date 27/11/1989 Ongoing at Study End K No

DataFax #220

Plate # 250

Visit # 253

Concomitant Medication

Subject Number 99999

Subject Initials 6

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT1 DOSTOT1 DOSU1 ROUTE1 C A AE, specify AE# 13
 Other: RSOTH1

Start date 18/02/1980 Stop date 23/07/1985 Ongoing at Study End
 Day Month Year Day Month Year F No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT2 DOSTOT2 DOSU2 ROUTE2 D B AE, specify AE# 14
 Other: RSOTH2

Start date 19/03/1981 Stop date 24/08/1986 Ongoing at Study End
 Day Month Year Day Month Year G No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT3 DOSTOT3 DOSU3 ROUTE3 E C AE, specify AE# 15
 Other: RSOTH3

Start date 20/04/1982 Stop date 25/09/1987 Ongoing at Study End
 Day Month Year Day Month Year H No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT4 DOSTOT4 DOSU4 ROUTE4 I A D AE, specify AE# 16
 Other: RSOTH4

Start date 21/05/1983 Stop date 26/10/1988 Ongoing at Study End
 Day Month Year Day Month Year J No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT5 DOSTOT5 DOSU5 ROUTE5 I B E AE, specify AE# 17
 Other: RSOTH5

Start date 22/06/1984 Stop date 27/11/1989 Ongoing at Study End
 Day Month Year Day Month Year K No

DataFax #220

Plate # 250

Visit # 254

Concomitant Medication

Subject Number 99999

Subject Initials 6

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT1 DOSTOT1 DOSU1 ROUTE1C1A AE, specify AE# 13
 Other: RSOTH1

Start date 18/02/1980 Stop date 23/07/1985 Ongoing at Study End
 Day Month Year Day Month Year F No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT2 DOSTOT2 DOSU2 ROUTE2DEB AE, specify AE# 14
 Other: RSOTH2

Start date 19/03/1981 Stop date 24/08/1986 Ongoing at Study End
 Day Month Year Day Month Year G No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT3 DOSTOT3 DOSU3 ROUTE3EDC AE, specify AE# 15
 Other: RSOTH3

Start date 20/04/1982 Stop date 25/09/1987 Ongoing at Study End
 Day Month Year Day Month Year H No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT4 DOSTOT4 DOSU4 ROUTE4IA D AE, specify AE# 16
 Other: RSOTH4

Start date 21/05/1983 Stop date 26/10/1988 Ongoing at Study End
 Day Month Year Day Month Year J No

Medication (generic name) Total dose (24 hours) Units Route Reason for use
 TRT5 DOSTOT5 DOSU5 ROUTE5IB E AE, specify AE# 17
 Other: RSOTH5

Start date 22/06/1984 Stop date 27/11/1989 Ongoing at Study End
 Day Month Year Day Month Year K No

	Comments	Subject Number <input type="text" value="99999"/>
		Subject Initials <input type="text" value="1"/>

Use this form to capture Study Information which cannot otherwise be collected in the Case Report Form (CRF). Indicate the CRF Visit number (just below the barcode) and the CRF Page number (lower right corner).

Visit Number	Page Number	Item on CRF	Comment
<input type="text" value="101"/>	<input type="text" value="109"/>	<input type="text" value="CRFITEM1"/>	<input type="text" value="ACDESC1"/>
<input type="text" value="102"/>	<input type="text" value="110"/>	<input type="text" value="CRFITEM2"/>	<input type="text" value="ACDESC2"/>
<input type="text" value="103"/>	<input type="text" value="111"/>	<input type="text" value="CRFITEM3"/>	<input type="text" value="ACDESC3"/>
<input type="text" value="104"/>	<input type="text" value="112"/>	<input type="text" value="CRFITEM4"/>	<input type="text" value="ACDESC4"/>
<input type="text" value="105"/>	<input type="text" value="113"/>	<input type="text" value="CRFITEM5"/>	<input type="text" value="ACDESC5"/>
<input type="text" value="106"/>	<input type="text" value="114"/>	<input type="text" value="CRFITEM6"/>	<input type="text" value="ACDESC6"/>
<input type="text" value="107"/>	<input type="text" value="115"/>	<input type="text" value="CRFITEM7"/>	<input type="text" value="ACDESC7"/>
<input type="text" value="108"/>	<input type="text" value="116"/>	<input type="text" value="CRFITEM8"/>	<input type="text" value="ACDESC8"/>

	Comments	Subject Number <input type="text" value="99999"/>
		Subject Initials <input type="text" value="1"/>

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<input type="text" value="101"/>	<input type="text" value="109"/>	<input type="text" value="CRFITEM1"/>	<input type="text" value="ACDESC1"/>
<input type="text" value="102"/>	<input type="text" value="110"/>	<input type="text" value="CRFITEM2"/>	<input type="text" value="ACDESC2"/>
<input type="text" value="103"/>	<input type="text" value="111"/>	<input type="text" value="CRFITEM3"/>	<input type="text" value="ACDESC3"/>
<input type="text" value="104"/>	<input type="text" value="112"/>	<input type="text" value="CRFITEM4"/>	<input type="text" value="ACDESC4"/>
<input type="text" value="105"/>	<input type="text" value="113"/>	<input type="text" value="CRFITEM5"/>	<input type="text" value="ACDESC5"/>
<input type="text" value="106"/>	<input type="text" value="114"/>	<input type="text" value="CRFITEM6"/>	<input type="text" value="ACDESC6"/>
<input type="text" value="107"/>	<input type="text" value="115"/>	<input type="text" value="CRFITEM7"/>	<input type="text" value="ACDESC7"/>
<input type="text" value="108"/>	<input type="text" value="116"/>	<input type="text" value="CRFITEM8"/>	<input type="text" value="ACDESC8"/>

	Comments	Subject Number <input type="text" value="99999"/>
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<input type="text" value="102"/>	<input type="text" value="110"/>	<input type="text" value="CRFITEM2"/>	<input type="text" value="ACDESC2"/>
<input type="text" value="103"/>	<input type="text" value="111"/>	<input type="text" value="CRFITEM3"/>	<input type="text" value="ACDESC3"/>
<input type="text" value="104"/>	<input type="text" value="112"/>	<input type="text" value="CRFITEM4"/>	<input type="text" value="ACDESC4"/>
<input type="text" value="105"/>	<input type="text" value="113"/>	<input type="text" value="CRFITEM5"/>	<input type="text" value="ACDESC5"/>
<input type="text" value="106"/>	<input type="text" value="114"/>	<input type="text" value="CRFITEM6"/>	<input type="text" value="ACDESC6"/>
<input type="text" value="107"/>	<input type="text" value="115"/>	<input type="text" value="CRFITEM7"/>	<input type="text" value="ACDESC7"/>
<input type="text" value="108"/>	<input type="text" value="116"/>	<input type="text" value="CRFITEM8"/>	<input type="text" value="ACDESC8"/>

	Comments	Subject Number <input type="text" value="99999"/> Subject Initials <input type="text" value="1"/>
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Visit Number	Page Number	Item on CRF	Comment
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<input type="text" value="102"/>	<input type="text" value="110"/>	<input type="text" value="CRFITEM2"/>	<input type="text" value="ACDESC2"/>
<input type="text" value="103"/>	<input type="text" value="111"/>	<input type="text" value="CRFITEM3"/>	<input type="text" value="ACDESC3"/>
<input type="text" value="104"/>	<input type="text" value="112"/>	<input type="text" value="CRFITEM4"/>	<input type="text" value="ACDESC4"/>
<input type="text" value="105"/>	<input type="text" value="113"/>	<input type="text" value="CRFITEM5"/>	<input type="text" value="ACDESC5"/>
<input type="text" value="106"/>	<input type="text" value="114"/>	<input type="text" value="CRFITEM6"/>	<input type="text" value="ACDESC6"/>
<input type="text" value="107"/>	<input type="text" value="115"/>	<input type="text" value="CRFITEM7"/>	<input type="text" value="ACDESC7"/>
<input type="text" value="108"/>	<input type="text" value="116"/>	<input type="text" value="CRFITEM8"/>	<input type="text" value="ACDESC8"/>