Physician Labeling

Fetoscopy Instrument Sets

Karl Storz Rigid TTTS Fetoscopy Instrument Set with 0 or 12 degree scope

- *HOPKINSII® Rigid Telescope (Models 26008AA, 26008FUA)*
- *Sheaths (Models 26161U, 26161CN, 26161CD)*

Karl Storz Rigid TTTS Fetoscopy Instrument Set with 30degree scope

- *HOPKINSII® Rigid Telescope (Model 26008BUA)*
- *Sheaths (Models 26161UF, 26161UH)*

Karl Storz Semi-Rigid TTTS Fetoscopy Instrument Set

- *Miniature Straight Forward Telescope (Model 11630AA)*
- *Sheaths (Models 11605F, 11630KF, 11630KH)*

Instruction Manual

Humanitarian Device. Authorized by Federal law for use in the treatment of twin-to-twin transfusion syndrome. The effectiveness of this device for this use has not been demonstrated.

Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician trained in selective laser photocoagulation for the treatment of twin-to-twin transfusion syndrome.

Fetoscopy Instrument Set Manual

Table of Contents

IMPORTANT Information for users of Karl Storz Instruments
Please read this entire manual carefully before using the Karl Storz Fetoscopy Instrument Sets. Failure to follow the Instructions, Warnings and Precautions presented in this manual may result in serious consequences to the patient. The procedures for proper handling and care of the Karl Storz Fetoscopy Instruments are described in this manual. The Karl Storz Fetoscopy Instruments are delicate surgical instruments and should be handled with care. Improper use during surgical procedures will result in damage or breakage. Karl Storz Endoscopy-America, Inc. assumes no liability if the instruments are misused, mishandled or otherwise abused. Proper handling and care, as described in this manual, will prolong the life of the Instruments. Recommended procedures for inspecting and preparing the instruments for use are described in this manual. **These instruments may only be used by licensed physicians and qualified personnel who have been trained in their use.**

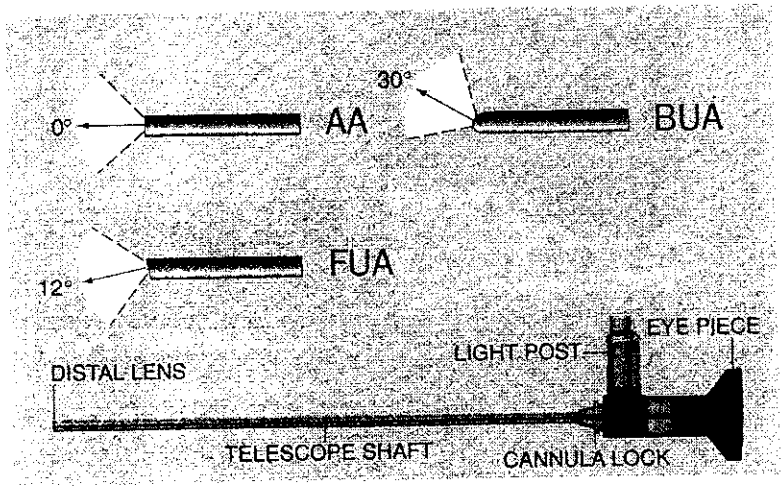
Consult medical literature relative to techniques, complications and hazards of endoscopic procedures.

Read all instructions, contraindications, warnings and precautions carefully prior to use.

Device Description
The TTTS Fetoscopy Instrument Sets consist of two rigid sets and a semi-rigid set. The Rigid TTTS Fetoscopy Instrument Set with 0 or 12 degree scope includes the HOPKINSII® telescope, single operating sheath, and continuous flow operating sheath set. The Rigid TTTS Fetoscopy Instrument Set with 30 degree scope includes the HOPKINSII® telescope and standard sheath set. The Semi-Rigid TTTS Fetoscopy Instrument Set consists of a miniature semi-rigid telescope, diagnostic sheath and two operating sheaths (needle shaped and blunt tip).
The HOPKINSII® rigid telescope and miniature semi-rigid telescope are available for use on both posterior and anterior located placentas. It is recommended that the physician determine which Set is more appropriate for the intended case of TTTS for treatment with S-LPC (Selective Laser Photocoagulation) based on the position of the placenta. The components of the sets are described below.

Rigid TTTS Sets

HOPKINSII® Model 26008 telescope



Specifications:

Letter code	Direction of View	
AA	0°	Straight Forward
BUA	30°	Forward-Oblique
FUA	12°	Telescopes

Rigid TTTS Set with 0 or 12 degree scope

- Model 26008 HOPKINSII® rigid telescope, autoclavable, 26 cm length, 2 mm diameter, and available in zero degree (model 26008AA) and twelve degree (model 26008FUA). It is a reusable rod lens telescope consisting of an eyepiece lens, a light post connection for fiber optic light cables with screw-on adapters which will accommodate light cables from other manufacturers. A shaft made of non-corrosive material encloses the rod-lens system and a built-in fiber optic light carrier.
- Single Lumen Rigid Sheath Set:
  - Model 26161U, Fetoscope Sheath, size 3 mm, 23 cm in length, 2.4 x 3.5 mm outer diameter, with pyramidal obturator, with channel for laser fibers with a core size of 400-600 microns and an outer diameter not to exceed 900 microns, with 1 stopcock and 1 LUER-Lock adaptor, for use with HOPKINSII® rigid telescope 26008 AA/FUA .
- Continuous Flow Rigid Sheath Set:
  - Model 26161CN, Fetoscope Sheath, size 4.3 mm, with working channel, 1.7 mm (use with laser fibers with a core size of 400-600 microns and an outer diameter not to exceed 900 microns,) , with 1 stopcock and 1 LUER-Lock adaptor, also for use as inner sheath with sheath 26161CD, for use with HOPKINSII® telescope 26008 AA/FUA.
  - Model 26161CD, Continuous-Flow Fetoscope Sheath, size 5 mm, with 1 stopcock and 1 LUER-Lock adaptor, for use as outer sheath with 26161CN.

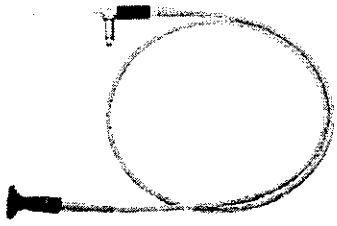
Rigid TTTS Set with 30 degree scope

- Model 26008 HOPKINSII® rigid telescope, autoclavable, 26 cm length, 2 mm diameter, and available in thirty degree (model 26008BUA). It is a reusable rod lens telescope consisting of an eyepiece lens, a light post connection for fiber optic light cables with screw-on adapters which will accommodate light cables from other manufacturers. A shaft made of non-corrosive material encloses the rod-lens system and a built-in fiber optic light carrier.

- Standard Rigid Sheath Set:
  - Model 26161UF, Fetoscope Sheath, size 3.8 mm, with pyramidal obturator, with channel for laser fibers with a core size of 400-600 microns and an outer diameter not to exceed 900 microns , with 1 stopcock and 1 LUER-Lock adaptor, also for use with sheath 26161 UH.
  - Model 26161UH, Working Insert with steering lever, for use with fetoscope sheath 26161 UF, for use with HOPKINSII® telescope 26008 BUA. The inner working sheath is equipped with a deflecting Albarran steering lever at the tip which enables deflection of the laser fiber towards the target.

Semi-rigid Set

Miniature Straight Forward Telescope Model 11630AA



- Model 11630AA, Miniature Straight Forward Telescope, 0 degree, semi-rigid, diameter 2 mm, working length 30 cm, autoclavable, with remote eyepiece, fiber optic light transmission incorporated, for use with sheath models 11605F, 11630KF, 11630KH.
- Model 11605, Fetoscope Sheath, diameter 3 mm, equipped with pyramidal obturator 11605FO, channel for laser fibers with a core size of 400-600 microns and an outer diameter not to exceed 900 microns, with 1 stopcock and 1 LUER-Lock adapter, for use with miniature telescope model 11630AA.
- Model 11630KF, Fetoscope Sheath, diameter 3 mm, needle-shaped, pointed tip, with working channel, size 1 mm, with 1 stopcock and 1 LUER-Lock adapter, for use with miniature telescope 11630AA.
- Model 11630KH, Fetoscope Sheath, diameter 3 mm, needle-shaped, blunt tip, with working channel, size 1 mm, with 1 stopcock, for use with miniature telescope 11630AA and laser fibers with a core size of 400-600 microns and an outer diameter not to exceed 900 microns,.

Use with Lasers

The Karl Storz fetoscopy instrument set telescopes are compatible for use with the following types of lasers using the recommended parameters listed below.

Table 1- Laser Compatibility

Laser type	Wavelength	Power Setting	Shot Duration	Laser Fiber Core Size	Laser Fiber Size (max outer diameter)
Nd:YAG laser	1064 nm	60 – 100 W	1-4 seconds	400-600 micron	900 micron
Diode laser	940 nm	30 – 60 W	1-4 seconds	400-600 micron	900 micron

Please refer to the laser operator's manual and any specific manual for laser delivery systems for complete instructions on the operation of the laser and the inspection of the laser and fiberoptic.

Principles of Operation

The Karl Storz Fetoscopy Instruments Sets are used in fetoscopic laser surgery. The specific instrument sets are for use in the selective laser photocoagulation of the connecting twin-to-twin blood vessels in TTTS. Only physicians with requisite training and skill should attempt selective laser photocoagulation for the treatment of TTTS.

The diagnosis of TTTS should be established prior to fetoscopy. Diagnostic criteria include: monochorionic placentation with visualization of a separating membrane, fetuses of the same sex, mid-pregnancy polyhydramnios-oligohydramnios sequence (polyhydramnios at the recipient's sac and oligohydramnios at the donor's sac), in the absence of other causes of abnormal amniotic fluid volume, and marked growth discordance.
In this procedure, the physican will introduce the fetoscopy instruments under ultrasound guidance by one of the following three options:

- with a trocar and cannula combination
- with a sharp-tip obturator and fetoscopy sheath
- with a sharp-tip sheath and telescope.

The instruments are inserted percutaneously through the maternal abdomen and uterine wall into the amniotic cavity of the recipient twin. After introduction, the telescope is either already in place or the trocar/obturator is removed and the telescope is inserted into the sheath/cannula. The placenta is surveyed using telescopes of the length and viewing angle preferred by the physician. The communicating vessels connecting recipient twin to donor twin are identified. A laser fiber with a 400-600 micron core diameter is introduced through the instrument channel of the sheath to ablate the connecting vessels.

At the end of fetoscopic surgery, excess amniotic fluid may be removed from the recipient twin.

Indication for Use

The Karl Storz Fetoscopy Instrument Sets are indicated for selective laser photocoagulation in the treatment of twin-to-twin transfusion syndrome for fetuses whose gestational age is between 16 and 26 weeks.

Contraindications

The Karl Storz Fetoscopy Instruments Sets are contraindicated for use in selective laser photocoagulation when the following conditions exist:

- ruptured membranes
- chorioamnionitis
- placental abruption or active labor.

The Karl Storz Fetoscopy Instrument Sets are also contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the mother or fetus.

Use of the Karl Storz Fetoscopy Instrument Sets is contraindicated whenever endoscopy is contraindicated.

Please read this manual carefully. It is very important that the user be thoroughly familiar with the operation of the instrument prior to use on a patient. The terms "Warning," "Precaution" and "Note" are intended to draw your attention to important parts of the instruction manual. All warnings, precautions and notes should be thoroughly reviewed prior to use of the instrument. Close attention to all warnings, precautions and notes is necessary for safe and effective operation of the device.

Definitions
WARNING: A warning indicates that the personal safety of the patient or physician may be compromised. Disregarding the warning may result in serious injury to the patient or the physician.
PRECAUTION: A precaution indicates that the device may be damaged if the precaution is disregarded.
Note: A note provides additional information regarding the safe operation of the device.

WARNINGS

- Selective laser photocoagulation may be hindered or impossible to perform in cases of TTTS patients with iatrogenic detached membranes (IDM) because of an inability to access the amniotic cavity with the trocar/fetoscope. IDM may occur after amniocenteses (1%) or operative fetoscopy (5-8%).[1]
- Large sized blood vessels must be coagulated with great care. To avoid the risk of iatrogenic perforation, refer to the appropriate power settings provided in Table 1, page 8.
- Only Nd:YAG and Diode lasers may be used with the Karl Storz Fetoscopy Instrument sets as they have been designated by Karl Storz as suitable for the 26008 series and 11630 telescopes.
- In cases in which the fetus may still be able to move do not fire the laser until the fetus moves away from the surgical field and consider use of a muscle-blocking agent.
- Never place the end of a laser fiber or telescope on or under a surgical drape while the light source unit is activated. The intensity of the light may cause burns to the patient and/or surgical drape.
- Always adjust the light source unit to the minimum illumination intensity necessary to achieve optimum illumination of the endoscopic scene, either by direct vision or coupled to a video camera. The higher the light intensity setting of the light source, the greater the heat energy that will be generated at the distal end of the telescope. When not in use, adjust light source to standby or initial mode.
- The surgical procedure should not continue if the image is unclear or limited.
- The laser fiber should be thoroughly inspected before each procedure, if any sign of damage is noted the laser fiber should be removed from service. Damaged laser fibers may result in inappropriate laser energy output at the fiber tip. Refer to manufacturers instructions for inspection of laser fibers.
- Excessive temperatures may be generated along the telescope if the wrong light cable is used. Use of the appropriate size light cable to minimize the heat energy generated from the light source. Refer to the Operating Instructions on page 28, a telescope with a diameter of 4 mm or less can accommodate a light cable of 2.5 mm or less.
- Performing selective laser photocoagulation in the presence of an anterior placenta may result in longer procedure times and failure to identify all communicating vessels.
- Amnioreduction prior to selective laser photocoagulation may complicate the selective laser photocoagulation by causing bloody discoloration of fluid (necessitating fluid exchange), perforation of the dividing membrane and possible membrane detachment.

[1] Quintero RA, Kontopoulos E, Chmait R, Bornick P, Allen M. Management of twin-twin transfusion syndrome in pregnancies with iatrogenic detachment of membranes following therapeutic amniocentesis and the role of interim amniopatch. Ultrasound Obstet Gynecol 2005;26:628-633.

WARNINGS: Cleaning and Sterilization

- Karl Storz HOPKINSII® rigid telescope, Miniature semi-rigid telescopes and sheaths are provided NON-STERILE and must be thoroughly cleaned and sterilized according to validated infection control procedures prior to use and subsequent reuse.
- Disinfection is NOT recommended for HOPKINSII® rigid telescope, Miniature semi-rigid telescopes and fetoscopy sheaths to be used for fetoscopic surgery procedures.
- Before sterilization, the HOPKINSII® rigid telescopes, Miniature semi-rigid telescopes and fetoscopy sheaths must be thoroughly cleaned and all organic material, blood and cleaning solution completely removed.
- Karl Storz HOPKINSII® rigid telescope, Miniature semi-rigid telescopes and sheaths are NOT sterilized and/or adequately rinsed when a sterile processing cycle is CANCELLED.
- Failure to thoroughly clean HOPKINSII® rigid telescopes, Miniature semi-rigid telescopes and fetoscopy sheaths may result in an ineffective sterilization process.

WARNINGS: STERRAD® Sterilization

- STERRAD® may be used only with sheaths that comply with the lumen size restrictions Lumens with inside diameters smaller than 3.0 mm CANNOT be processed in the STERRAD® sterilizer. Consult the STERRAD® user's manual prior to use.

WARNINGS: STERIS® Sterilization

- Sterility of Karl Storz sheaths cannot be assured using the STERIS PROCESS™.
- During STERIS® sterilization processing only use STERIS® recommended containers to ensure proper sterilization of the telescopes. Consult the STERIS® manual prior to use.
- During the STERIS® process failure to properly position telescopes so that all surfaces will be exposed to the sterilant or overloading the processing container may result in an ineffective sterile process and/or damage to the devices.
- DO NOT use the STERIS® system for telescopes that cannot be immersed in liquid.
- Always verify that the sterilant container is empty after the cycle is complete. If the sterilant container is NOT empty, then the load CANNOT be considered sterile.

WARNINGS: STEAM Sterilization

- ONLY KARL STORZ TELESCOPES and instruments marked "AUTOCLAV" can be steam sterilized.

PRECAUTIONS

- The outer diameter (OD) of laser core fibers should be a maximum of 900 micron to fit the working channel of the sheaths designated in the Karl Storz Fetoscopy Instrument Sets.
- The safety and effectiveness of selective laser photocoagulation compared with amnioreduction in treating Stage 1 TTTS have not been demonstrated in controlled clinical studies. The physician must exercise caution and clinical judgment when selecting treatment options for mild versus severe cases of TTTS.
- The safety and effectiveness of the device/procedure beyond 26 weeks gestational age is not known. As the size of vascular communications on the surface of the placenta increases with gestational age, the risk of rupture and hemorrhage during photocoagulation increases.

- Make sure the stopcock is fully open while the laser fiber is in place to prevent any damage to laser fiber coating.
- The laser fiber should be maintained at a distance of not less than 5 mm from the end of the sheath. At this distance the laser fiber extends beyond the tip of the endoscope while under direct vision by the surgeon and prevents damage or burning of the sheath. The operator should remain in visual control of the direction and pathway of the laser beam.
- The distal ends of the HOPKINSII® rigid and Miniature semi-rigid telescopes are very sensitive and can be easily damaged. Introduction through or into sheaths, trocars, etc. must be done carefully. In case of blockage, do not attempt to penetrate the blockage using the distal tip.
- Always hold Miniature semi-rigid telescopes by the eyepiece, never by the shaft alone.
- Handle the HOPKINSII® rigid and Miniature Semi-rigid telescopes carefully. Hard blows, particularly to the distal end, may damage the distal lens system or image bundle. Always keep telescopes in their protective cases when not in use.
- At the distal end of the semi-rigid telescope is a rigid lens system of approx. 10 mm length. If the telescope is bent in this area, this can lead to a break in the lens system.
- Do not use the HOPKINSII® rigid telescopes or Miniature semi-rigid telescopes if there are any visible signs of damage. Telescopes must be replaced if the image is cloudy, there is no image or only a partial image can be seen.

- Do not use the fetoscopy sheaths if visible signs of damage are present. If there is any doubt about whether the instruments are safe to use, please contact the Technical Support Staff directly at Karl Storz (1-800-421-0837).
- To ensure the long lasting quality of the fetoscopy sheaths, please follow the handling instructions described below.
  1. To prevent damage or injury, always support the instrument by firmly grasping the proximal end of the shaft.
  2. Never place heavy items on top of the instruments.
  3. Always protect the tip of the sharp sheath.

PRECAUTIONS: Cleaning and Sterilization

- DO NOT soak the HOPKINSII® rigid and Miniature semi-rigid telescopes in any solution (including water) for longer than 60 minutes.
- WEAR PROTECTIVE GLOVES, CLOTHING AND A FACE MASK FOR CLEANING OF CONTAMINATED Fetoscopy Instruments.
- DO NOT clean the Karl Storz HOPKINSII® rigid and Miniature semi-rigid telescopes in an ultrasonic bath.
- The recommended sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.
- Cleaning with the cleaning paste should only be done if the image is cloudy (after approximately 10 to 20 sterilizations) and not as part of the routine cleaning.
- During sterilization, HOPKINSII® rigid and Miniature semi-rigid telescopes and sheaths should not come into direct contact with metal.
- Any deviations from the recommended parameter for sterilization shall be validated by the user.

PRECAUTIONS: STERRAD® Sterilization

- STERRAD® sterilization may cause cosmetic changes to the HOPKINSII® telescopes, miniature semi-rigid telescopes and fetoscopy sheaths that do not necessarily impact the functionality of the device.
- The HOPKINSII®, miniature semi-rigid telescopes and sheaths must be thoroughly DRIED before loading into the STERRAD® System chamber. Loads containing moisture may cause a cycle cancellation.
- Use only STERRAD® Instrument trays in the sterilization chamber. These trays are specially designed to allow the plasma to surround the items. During STERRAD® sterilization only use polypropylene sterilization wrap and polyolefin pouches. Do not use paper pouches or sterilization wraps containing wood pulp or cotton.
- Any deviations from the recommended STERRAD® System sterilization parameters must be validated by the user.

PRECAUTIONS: STEAM Sterilization

- Never attempt to cool telescopes by pouring cool, sterile liquid over the HOPKINSII® telescopes or miniature semi-rigid telescopes. Forced cooling will cause severe damage to the telescope.

Adverse Events

The following adverse events have been reported or can potentially occur with the use of the Fetoscopy Instrument Sets:

Maternal Complications

- Wound infection
- Chorioamnionitis
- Chorioamniotic separation
- Amniotic fluid leakage into abdomen resulting in pain or discomfort
- Amniotic fluid embolism
- Placental abruption
- Bleeding/hemorrhage
- Complications from severe bleeding
- Inability of have future children
- Hysterectomy
- Maternal death
- Complications/side-effects of anesthesia (Epidural anesthesia and General anesthesia)
- Pre-term labor
- Mirror Syndrome

Fetal Complications

- Chorioamniotic separation
- Neurological complications or other forms of brain damage may occur (such as subchorionic hematoma)
- Complications of prematurity
- Fetal injury during entry due to accidental penetration of the placenta by instruments
- Morbidity after birth
- Incomplete coagulation of communicating vessels (recurrent TTTS)
- Subchorionic hematoma
- Preterm rupture of fetal membranes
- Ileal atresia
- Limb necrosis
- Congenital skin loss
- Need for transfusion of one or both fetuses
- Need to sacrifice one fetus to save the other fetus
- Fetal death - intrauterine or neonatal
- Fetal bradycardia

PIVOTAL CLINICAL TRIAL

Eurofetus Clinical Trial[ii]

Purpose: To compare the safety and efficacy of two different treatment methods in severe TTTS before 26 weeks 0 days gestation. The study was designed to examine whether selective laser photocoagulation of anastomoses using the Karl Storz Fetoscopy Set, is superior to serial amnioreduction in the treatment of TTTS. (Published studies on laser photocoagulation in the treatment of TTTS have highlighted a distinction between non-selective and selective laser photocoagulation between communicating vessels.[iii] In the Eurofetus Study, selective laser photocoagulation was performed).

Endpoints:
The primary outcome measures, included:

- Perinatal (within 28 days) survival of at least one twin
- Survival of at least one twin to 7-12 months of age
- Clinically significant neurologic complications (i.e., severe intraventricular hemorrhage (grade III or IV), cystic periventricular leukomalacia, blindness and deafness) at 7-12 months of age.

Secondary outcome measures included:

- maternal and obstetrical complications associated with either treatment
- fetal complications

Methods: A prospective, randomized (1:1), open-labeled, multi-center, international study was conducted at seventeen centers in 6 countries. Pregnant women with severe TTTS between 15 and 26 weeks gestation were randomly assigned to selective laser photocoagulation or serial amnioreduction. While all centers performed amnioreduction, only 3 of the 17 centers with the appropriate Karl Storz equipment performed selective laser photocoagulation. The equipment used included the Karl Storz miniature semi-rigid 11630 telescope (and associated sheaths), along with a neodymium:yttrium-aluminum-garnet (Nd:YAG) or diode laser with a fiber diameter of 400-600 microns, with laser power output between 30-60W. The study included 142 patients diagnosed with TTTS. Study subjects were required to meet the following inclusion/exclusion criteria:

[ii] Senet, Deprest, Boulvain, Paupe Winer, Ville. Endoscopice Laser Surgery versus Serial Amnioreduction for Severe Twin-to-Twin Transfusion Syndrome. N Engl J Med 2004;351:136-44.
[iii] Obido AO and Macones GA. Management of twin-twin transfusion syndrome: laying the foundation for future interventional studies. Twin Research 2002:5(6):515-20.

Inclusion Criteria

- Pregnant women between 15 and 26 weeks gestation with severe TTTS
- Polyuric polyhydramnios in the recipient twin with the deepest vertical pool measuring at least 8.0 cm at or before 20 weeks gestation or 10.0 cm after 20 weeks gestation
- A distended fetal bladder in the recipient twin
- Oliguric oligohydramnios in the donor twin, with the deepest vertical pool measuring at most 2.0 cm

Exclusion Criteria

- Fetal death
- A major fetal anomaly
- Ruptured membranes
- A maternal condition mandating delivery
- Any previous invasive therapy for the syndrome

The selective laser photocoagulation procedure was completed with amnioreduction, removing fluid to levels at or just below normal.

Interim Analyses: The study design included two interim analyses after enrollment of 72 and 144 women. The purpose of the interim analyses was to evaluate the rate of survival of at least one twin to discharge from the neonatal intensive care unit (NICU).

Demographics:

Table 2 summarizes important demographic information:

Table 2 – Patient Demographics

	Selective Laser Photocoagulation (S-LPC) (N=72)	Amnioreduction (N=70)
Gestational age at randomization (weeks)	20.6 ± 2.4	20.9 ± 2.5
Location of placenta- no. (%)		
Anterior	30 (42%)	40 (57%)
Posterior	42 (58%)	30 (43%)
Quintero stage – no. (%)		
Stage 1 (abnormal amniotic fluid levels alone)	6 (8%)	5 (7%)
Stage 2 (collapsed bladder in donor)	31 (43%)	31 (44%)
Stage 3 (abnormal Doppler flow in either twin)	34 (47%)	33 (47%)
Stage 4 (hydrops in either twin)	1 (1%)	1 (1%)

At inclusion, the groups were similar with respect to demographic, clinical and ultrasonographic characteristics except for an imbalance in placental location, with more posterior insertions in the laser group than in the amnioreduction group.[iv]

[iv] Senet, Deprest, Boulvain, Paupe, Winer, Ville: Endoscopic Laser Surgery versus Serial Amnioreduction for Severe Twin-to-Twin Transfusion Syndrome. N Engl J Med 2004; 351:136-44.

Table 3 -Subject Accountability

	Selective Laser Photocoagulation (S-LPC)	Amnioreduction
Subjects Randomized	N=72	N=70
Fetal death prior to treatment	-1	-1
Did not meet study criteria after evaluation	-2	0
Subject withdrew consent	0	-1
Subjects treated	N=69	N=68

Summary of Results

Primary Outcome Measures

The planned interim analysis showed that selective laser photocoagulation was associated with a significantly higher rate of survival of at least one infant to discharge from the NICU. This outcome was considered to be more clinically relevant than survival at 28 days which was one of the three original primary outcome measures. None of the infants died after being discharged from the NICU, and thus the rate of discharge from the NICU was the same as the rate of survival of at least one twin to 6 months. The rate of survival of at least one twin and clinically significant neurologic complications at six months, as presented in the table, are likely to be representative of those obtained with 7-12 month follow up as stated in the original primary outcome measures. Since the study was concluded early there was no data provided on the primary outcome measure related to survival at 7-12 months.

Table 4 – Primary Outcome Measures

	Laser	**Amnioreduction**	**p-value**
Perinatal survival to 28 days	55/72 (76%)	39/70 (56%)	0.009
Survival of at least one twin to at least 6 months ▪ 1 survivor ▪ 2 survivors	55/72 (76%) 29/72 (40%) 26/72 (36%)	36/70 (51%) 18/70 (26%) 18/70 (26%0	0.002
Intraventricular hemorrhage (IVH) (grade III or IV)† Donor Recipient	2/144 (1%) 2/72 (3%) 0/72	8/140 (6%) 2/70 (3%) 6/70 (9%)	0.10** 1.0 0.02
Cystic periventricular leukomalacia‡ Donor Recipient	8/144 (6%) 2/72 (3%) 6/72 (8%)	20/140 (14%) 5/70 (7%) 15/70 (21%)	0.02**
Blindness *	2/144 (1%)	1/140 (0.71%)	0.576
Deafness	0/144	0/140	1.00

†Severe IVH was defined as ventricular bleeding with dilatation of the cerebral ventricles (grade III) or parenchymal hemorrha (grade IV)

‡ Cystic periventricular leukomalacia was defined as periventricular densities evolving into cystic lesions (grade III) or extending into the deep white matter and evolving into cystic lesions (grade IV).

*The reported cases of blindness may represent cases included elsewhere in the table, i.e., intraventricular hemorrhage

** This analysis was adjusted for clustering between twins

Secondary Outcome Measures
Safety was assessed through the occurrence of maternal and obstetrical complications and fetal morbidity (other than neurological).

Table 5 - Maternal and Obstetrical Complications

	Laser N=69	Amnioreduction N=68	p-value
Placental abruption	1/69 (1%)	2/68 (3%)	0.62
Intraabdominal leakage of amniotic fluid†	2/69 (3%)	0	0.50
Pregnancy loss within 7 days after initial procedure	8/69 (12%)	2/68 (3%)	0.10
Preterm rupture of membranes (PROM) within 7 days of initial procedure	4/69 (6%)	1/68 (1%)	0.37
Preterm rupture of membranes(PROM) and fetal death within 7 days of procedure	4/69 (6%)	1/68 (1%)	0.37
PROM and fetal death within 28 days of procedure	6/69 (9%)	6/68 (9%)	0.98
	N=138	N=136	
Intrauterine death within 7 days of initial procedure	16/138 (12%)	9/136 (7%)	0.23

† Abdominal pain related to intraabdominal leakage of fluid through the uterine puncture was managed expectantly and resolved in the two women in the laser group.

Overall, the selective laser photocoagulation subjects had better long-term outcomes than the amnioreduction subjects. However, as noted in Table 5, amnioreduction subjects had better short-term outcomes in the categories pregnancy loss within seven days, PROM within seven days and intrauterine death within seven days of the initial procedure. These differences were not, however, statistically significant.

Other Outcome Measures:

Table 6- Other Outcome Measures

	Laser N=72	Amnioreduction N=70	p-value
Gestational age at delivery (no. of pregnancies)			0.003*
< 24 wk	12	8	
24 to <27 wk	9	22	
28 to 31 wk	9	18	
32 to < 33 wk	9	7	
34 to 35 wk	17	11	
≥ 36 wk	16	4	
Median gestational age at delivery	33.3	29.0	0.004
Mean birth weight (g)**	1757	1359	< 0.001
Median total volume of amniotic fluid drained and range (mL) †	1725 (500-5500)	3800 (600-18,000)	< 0.001

*The Chi-square test was used with 5 degrees of freedom.
** These values are based on liveborn infants.
†This data does not include 5 women (3 Laser and 2 Amnioreduction) who did not undergo the assigned procedure.

The authors only reported on neonatal neurological morbidity. Neonatal morbidity associated with pulmonary, intestinal, or other organ systems are therefore not presented here.[v,vi,vii,viii,ix]

A Reference list for the Eurofetus Clinical Trial and publications addressing both Selective Laser Photocoagulation (S-LPC) and Amnioreduction are provided in Appendix II.

Patient Preparation
Karl Storz recommends providing each patient with our patient information brochure, "Selective Laser Photocoagulation for treatment of Twin-to-Twin Transfusion Syndrome". This brochure is designed to provide additional information to the patient for treatment of selective laser photocoagulation with Karl Storz Fetoscopy Instrument Sets for TTTS. This brochure is not intended to replace other literature or information provided to the patient by the physician/health facility.

Inspection

Inspection of the Telescopes:
Inspection of the telescopes for signs of damage should be performed before and after every surgical procedure.

Inspection of the Working Shaft:
Inspect the entire surface of the working shaft of the telescope for any signs of damage such as dents, bends or scratches.

Inspection of the Objective Lens and Eyepiece:
Inspect the objective lens (distal tip) and eyepiece for scratches, chips, fingerprints or residual debris by observing the reflected light on the surfaces of the eyepiece and objective lens. These surfaces should be smooth and shiny. To check for clarity of view slowly rotate the telescope while looking through the eyepiece. A partially or completely obstructed view may be the result of a damaged lens within the eyepiece or within the telescope shaft. Foggy images may result from moisture entering a damaged seal around the lens.

Inspection of the sheaths:
Inspection of the Karl Storz sheaths for signs of damage should be performed before and after every surgical procedure. All moving parts, such as stopcocks and LUER-lock adaptor should be easily operable and free of blemishes. The surfaces and lumen of the sheaths should be smooth and free of blemishes. The shaft of the sheath should be straight.

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[v] Senet, Deprest, Boulvain, Paupe, Winer, Ville: Endoscopic Laser Surgery versus Serial Amnioreduction for Severe Twin-to-Twin Transfusion Syndrome. N Engl J Med 2004; 351:136-44.

[vi] Odibo AO and Macones GA. Management of twin-twin transfusion syndrome: laying the foundation for future interventional studies. Twin Research 2002;5(6):515-520.

[vii] Ibid, pages 515-520.

[viii] Lundvall L, Skibsted L, Graem N. Limb necrosis associated with twin-twin transfusion syndrome treated with YAG-laser coagulation. Acta Obstretrica Gynecologica Scandinavica 1999; 78:349-350)

[ix] Stone CA, Quinn MW and Saxby PJ. Congenital skin loss following Nd:YAG placental photocoagulation. Burns 1998; 24: 275-277.

Directions for Use

Karl Storz Fetoscopy Instrument Set for Twin-to-Twin Transfusion Syndrome (TTTS)

The Karl Storz Fetoscopy Instrument Sets have been used in operative fetoscopy for Twin-to-Twin Transfusion in a European study, The EuroFetus Study. The following is a description of the basic principles and techniques used by selected authors experienced in operative fetoscopy using the Karl Storz Fetoscopy Instrument Set: (references provided in Appendix II).[24, 27, 30, 31, 33, 36, 38, 39] This section of the labeling is intended as a general overview only and is not intended to prescribe how selective laser photocoagulation should be performed. Each case of TTTS has unique features (e.g. placental position) and vascular anastomoses that will have to be managed somewhat differently. Furthermore, this section is not a substitute for physician training. Only physicians with requisite training and skill should attempt selective laser photocoagulation.

I. Basic Principles of Operative Fetoscopy and Access to the Amniotic Cavity

The endoscope is placed inside a sheath. The laser fiber can be inserted via the instrument port into the sheath. The distal end of the sheath is more narrow than the proximal end in order to maintain the fiber in a stable position. Luer lock connections allow for irrigation or drainage of fluid. The sheath can either be introduced directly or through a cannula. For direct introduction the sheath is loaded with its accompanying trocar (e.g., a sharp obturator). Under ultrasound guidance the sheath and trocar pierce through the abdominal wall, myometrium and membranes of the recipient twin. And once inside the amniotic sac, the obturator is withdrawn and replaced by the appropriate endoscope. During the procedure, the sheath and scope are moved back and forward according to the needs of the procedure, but cannot be withdrawn without giving up access to the amniotic cavity.

Using sheaths/cannulas with ports through which instruments and endoscopes may be introduced repeatedly permits changing of the instruments and may reduce the risk of membrane dislodgement since the cannula remains in place in the membrane during the procedure.

When working in a natural amniotic fluid environment, vision may be hampered by blood or debris. Less than optimal vision is described in approximately 5% of fetoscopic laser procedures for TTTS. In some cases, replacement of amniotic fluid may be needed. Warm Ringer's Lactate has been used as replacement fluid

Energy sources are needed to coagulate the identified blood vessels. Both Nd:YAG laser (minimal power requirements 60-100W) and diode laser (30-60W) with fiber of 400 to 600 microns have been used. Refer to page 8 of this Instruction Manual for Karl Storz recommended parameters for fetoscopy endoscope models 26008 and 11630 with Nd:YAG laser and Diode laser.

II. Operative Fetoscopy Technique for Twin-to-Twin Transfusion Syndrome

Video equipment that simultaneously displays both ultrasound and endoscopic images is recommended for selective laser photocoagulation procedure. The telescope and accompanying sheath used should to be chosen based on the actual positioning of the placenta. Typically Karl Storz 2.0 mm rod lens or fiber-optic endoscopes with a 0° direction of view have been used. The fetoscopy sheath has an instrument channel to accommodate the use of the laser fiber. The laser energy source typically is either a Nd:YAG or diode laser with 400 or 600 µm laser fibers. Procedures are done under direct visualization.

1. ***Identification of the fetuses and placenta.*** *Ideally the scope should enter the amniotic cavity of the recipient twin in the polyhydramnios sac, and then be directed at a 90° angle to the longitudinal axis of the donor twin. Use of this technique will increase the likelihood that a perpendicular position in relation to the inter-twin membranes can be obtained.*

2. ***The placental cord of the twins must be carefully searched and mapped.*** *The entry site should enable a maximum overview of the surface of the placenta in between the two cords, with minimal angulation of the scope. The vascular equator of the placenta will most likely be on the placental surface between the two cords.*

3. ***Avoiding the placenta, fetal parts and major maternal vessels.*** *The placenta is often flattened by the polyhydramnios and the edges cannot always be discriminated with certainty before amnioreduction. Additional important landmarks include the position of the cord insertion and the position of the donor twin.*

When the placenta is anterior allowing only lateral access, one should not take the risk of maternal injury to the uterine or broad ligament vessels. In the case of anterior placenta, one may enter the scope towards the placenta trying to avoid the richly vascularized area in case the edge of the placenta is entered inadvertently. All landmarks should be identified using color Doppler sonography.

4. ***After vascular anastomoses have been identified, coagulation is performed*** *at a distance of approximately 1 cm and ideally at a 90° angle, avoid touching the vessel at anytime. Laser shots of about 3 to 4 seconds, according to tissue response, are performed on one cm sections of the vessel. Laser energy should be set according to the source used, the diameter of the vessels, and the tissue response. Typically a Nd:YAG laser would be set at 50 to 70 W or a diode laser at 30 to 40 W. Large vessels (>3 mm) can be approached at various angles to progressively obtain narrowing and ultimately coagulation of the vessel. Large-sized vessels are susceptible to the risk of iatrogenic perforation when treated at excessive laser power levels, as was demonstrated in experiments. Once all vessels are coagulated, the operative sites must be reinspected to ensure that coagulation has been effective.*

Handling of Telescopes

CAUTION: The distal end of a telescope is delicate and can be easily damaged. Introduction through or into trocars, sheaths, etc. must be done carefully. In case of blockage, do not attempt to penetrate the blockage using the distal tip.

Handling of HOPKINSII® Rigid Telescopes

Karl Storz HOPKINSII® rigid telescopes are delicate instruments. To ensure the long lasting quality of the telescope, please follow the handling instructions described below.

1. To prevent breakage, the telescope should be supported by firmly grasping the eyepiece end. Never handle the telescope by the distal end alone.
2. Never bend the stainless steel shaft. This could lead to breaks or cracks in the rod lens system.
3. Handle the telescope with care. Mishandling of the telescope, particularly at the distal end, may result in damage or cracks in the telescope. Damage to the telescope may allow liquid and other materials to penetrate causing unclear images.
4. When cleaning and sterilizing the telescope, Karl Storz recommends that it be handled separately from other instruments.
5. Protective cases, which are suitable for storage, transport and sterilization, are available in various lengths for Karl Storz HOPKINSII® rigid telescopes.

Handling of Miniature Semi-Rigid Telescopes

The optical section of Karl Storz miniature semi-rigid telescope consists of a fiberoptic bundle in a flexible and watertight sheathing, a light guide, an objective lens and remote eyepiece lens. These parts are very delicate. For this reason, careful handling of the telescope is essential for a long service life and a consistent quality. To prevent breakage of optical fibers, do not kink or tightly coil the light guides.

Handling of Sheaths

To ensure the long lasting quality of the sheaths, please follow the handling instructions described below.

1. To prevent damage or injury, always support the instrument by firmly grasping the proximal end of the shaft.
2. Never place heavy items on top of the instruments.
3. Always protect the tip of the sharp sheath by leaving the blunt obturator inside the sheath when not in use.

Operating Instructions

1). Verify that the telescope has been properly cleaned and sterilized prior to use. (See Cleaning and Sterilization section for detailed procedures).
2). Inspect the telescope for damage and proper function as described above.
3). Operate all video and light source equipment in accordance with manufacturer's instructions.
4). Prepare the surgery entry site in accordance with proper endoscopic surgical techniques. Consult the appropriate medical literature.
5). Attach the light cable to the fiber optic light post on the telescope. Karl Storz recommends that the appropriate size light cable be used to minimize the heat energy generated from the light source. Use of the appropriate size light cable will reduce the risk of patient burns, as well as the risk of igniting flammable material. For the telescopes used in the fetoscopy instrument sets, use a light cable size 2.5 mm or less.

Anchoring the Laser Fiber

For anchoring the rigid scope model 26008AA, Karl Storz recommends using the Standard Sheath Set, models 26161UH and 26161UF. The inner sheath (26161UH) has a working channel for the laser fiber. At the tip of this sheath an Albarran delecting mechanism holds the fiber which enables deflecting the laser fiber toward the target. The external sheath (26161UF) protects the deflecting mechanism, working channel and laser fiber.

For anchoring the miniature semi-rigid telescope model 11630AA, Karl Storz recommends use of the Karl Storz ALKEN Motion Control Device, model 26022 MA. This accessory can be attached to the irrigation or instrument channel and enables precision introduction and fixation of the laser fiber by advancing the fiber in 1/10 mm steps.

Cleaning and Sterilization Instructions

WARNING: Karl Storz HOPKINSII® rigid telescopes, Miniature semi-rigid telescopes and sheaths are provided NON-STERILE and must be thoroughly cleaned and sterilized according to validated infection control procedures prior to use and subsequent reuse.

Preparation for Cleaning and Sterilization of HOPKINSII® and Miniature Semi-rigid Telescopes

1). Disconnect the light cable from the telescope.
2). Remove the light cable adapters.
3). Place the disassembled instruments in containers and soak with a neutral pH (pH 6.0 to 8.0) enzymatic cleaning solution (e.g., Enzol, Metrizyme or equivalent per manufacturer's instruction) immediately after use to prevent blood, protein and other contaminants from drying onto the instruments. Do not soak telescopes with other instruments to prevent damage to the telescope.

Water Quality Requirements

Distilled water is recommended for cleaning and rinsing of all instruments.

Cleaning Instructions for HOPKINSII® and Miniature Semi-rigid Telescopes

1). Remove light cable adapters before cleaning and sterilization. Do not clean or rinse telescopes with other instruments to prevent damage to the telescope.

2). Remove any residual blood, protein material and contaminants with sponges, soft cloths or a cotton cloth applicator using a neutral pH (pH 6.0 to 8.0) enzymatic cleaning solution (e.g. Enzol, Metrizyme or equivalent per maufacturer's instructions) and distilled water. Karl Storz does not recommend the use of detergents alone, as they contain high concentrations of surfactants which can leave a film on the telescopes. See Appendix I for available Karl Storz cleaning accessories.

3). Clean the lenses and fiber optic inlet post with alcohol wipes or sterile cotton tip applicators with 70% alcohol to remove any residue or film left after cleaning.

4). Triple-rinse the telescope with distilled water, for a minimum of one minute for each rinse. The rinse water should be discarded at the end of each rinse, as it will be contaminated with the cleaning solution. Thorough rinsing of the telescope is necessary to remove any debris or detergent which could interfere with sterilization.

5). Dry the telescope with a lint-free soft cloth or filtered compressed air.

6.) After cleaning, inspect the telescope for cleanliness and damage as described above.

7). Special Instructions for cleaning autoclavable telescopes: telescopes that have been autoclaved many times may develop deposits on the glass surfaces. To remove the deposits, clean the telescope with Karl Storz cleaning paste 27661). Put a small amount of cleaning paste on a moist cotton swab and lightly spread it on the glass surface. Rub gently to remove any stubborn deposits.

8). After polishing with the cleaning paste, thoroughly rinse the glass surfaces with water. Clean the surfaces with 70% alcohol or alcohol wipes to remove all traces of the cleaning paste. It may be necessary to repeat steps 2 to 5 above to ensure all of the cleaning paste is removed.

9.) After cleaning, inspect the telescope for cleanliness and damage as described above.

Cleaning Instructions for Sheaths

Force water through the lumen of the sheath to ensure that blood and debris are removed.

1. Disassemble all stopcocks.
2. Thoroughly rinse the sheaths to remove all gross debris. Be sure to thoroughly rinse the inside of the sheath, by forcing water through the lumen. This will remove any debris accumulated.
3. Manual cleaning is recommended. However, difficult to reach areas such as lumens and stopcocks can be cleaned using an ultrasonic cleaner for a maximum of 5 minutes. It is important to follow the manufacturer's instructions for operating the ultrasonic cleaner.
4. Completely immerse the instruments in a neutral pH enzymatic cleaning solution (e.g. Enzol, Metrizyme or equivalent per manufacturer's instructions) and distilled water. Be sure that the lumen of the sheath is completely filled with cleaning solution. Karl Storz does not recommend the use of detergents alone, as they contain high concentrations of surfactants which can leave a film on the instruments.
5. Remove any residual blood, protein material and contaminants from the sheath with brushes, sponges, soft clothes or a cotton cloth applicator. Cleaning accessories are available from KSEA.
6. Clean the surface of the instruments with a soft brush. Clean the inside of the stopcocks with a short cleaning brush. Clean the inside of the sheaths with the appropriate size cleaning brushes.
7. Cleaning brushes should be cleaned and high level disinfected or sterilized daily.
8. Triple-rinse all instruments with distilled water, for a minimum of one minute for each rinse. The rinse water should be discarded at the end of each rinse, as it will be contaminated with the cleaning solution. Thorough rinsing of the instruments is necessary for removing any debris or detergent which could interfere with sterilization. Cleaning pistols (Karl Storz part number 27660) with the smallest attachments are useful for rinsing the instruments.

Cleaning Instructions for Sheaths, continued

9. Dry the instruments with a lint-free soft cloth or filtered compressed air. To insure that debris and water are removed from the stopcocks of all sheaths, purge stopcock openings, alternately with water and filtered compressed air. Cleaning pistols (Karl Storz part number 27660) with the smallest attachments are useful for drying the instruments with compressed air.
10. After cleaning, inspect the instruments for cleanliness and damage.
11. Before sterilization, lubricate all moving parts of the sheaths with a non-silicone water soluble instrument milk or lubricant (e.g. Codman Preserve per manufacturer's instructions). Silicone or oil-based lubricants are not recommended for use because sterilants cannot penetrate the silicone or oil.

Sterilization Instructions for Fetoscopy Instrument Sets

Routine steam sterilization is recommended for initial and subsequent sterilization of the Fetoscopy Instrument Sets. The instruments may also be STERRAD® or STERIS sterilized, with exception of the fetoscopy sheaths. Karl Storz can not assure sterility of the sheaths with the STERIS Process™. STERRAD® may be used only with sheaths that comply with the lumen size restrictions detailed in the STERRAD® System section, below. To achieve the desired sterility assurance level (SAL) of 10^{-6}, Karl Storz recommends the following steam, STERRAD® or STERIS sterilization methods.

WARNING: Karl Storz HOPKINSII® telescopes, Miniature semi-rigid telescopes and sheaths are provided NON-STERILE and must be thoroughly cleaned and sterilized according to validated infection control procedures prior to use and subsequent reuse.

WARNING: Before sterilization, Karl Storz HOPKINSII® rigid telescopes, Miniature semi-rigid telescopes and sheaths must be thoroughly cleaned and all organic material, blood and cleaning solution completely removed".

Sterilization using the STERRAD® System

The STERRAD® System utilizes a synergism between hydrogen peroxide and low temperature gas plasma to produce a rapid, low temperature (50 - 104°F), low moisture inactivation of microorganisms.

WARNING: STERRAD® may be used only with sheaths that comply with the lumen size restrictions lumens with inside diameters smaller than 3.0 mm CANNOT be processed in the STERRAD® sterilizer. Consult the STERRAD® user manual for complete instructions for use.

CAUTION: STERRAD® sterilization may cause cosmetic changes to the devices that do not necessarily impact the functionality of the device.

CAUTION: All instruments must be thoroughly DRIED before loading into the STERRAD® System chamber. Loads containing moisture may cause a cycle cancellation.

Sterilization using the STERRAD® System, continued

CAUTION: Only use STERRAD® Instrument trays in the sterilization chamber. These trays are specially designed to allow the plasma to surround the items.

CAUTION: During STERRAD® sterilization only use polypropylene sterilization wrap and polyolefin pouches. Do not use paper pouches or sterilization wraps containing wood pulp or cotton.

CAUTION: Any deviations from the recommended STERRAD® System sterilization parameters must be validated by the user.

Note: Instruments that Karl Storz has determined to be compatible with the STERRAD® System sterilization process have been validated with one hundred STERRAD® System cycles.

1). Clean and thoroughly dry all instruments. Stopcocks do not have to be fully disassembled, but should be in the open position during sterilization.
2). Place the instruments in the STERRAD® instrument trays, wrap in polypropylene sterilization wrap or enclose in polyolefin pouches. Place STERRAD® indicator strips in all trays and pouches.
3). When loading the STERRAD® sterilizer, arrange the items such that the hydrogen peroxide plasma can surround them. Do not allow any items to touch the wall of the sterilizer.
4). Please consult the STERRAD® System Operators Manual for detailed instructions for use.

Sterilization Instructions for HOPKINSII® Rigid Telescopes and Miniature Semi-Rigid Telescopes

Sterilization using the STERIS PROCESS™

The STERIS PROCESS™ is a sterile processing method for immersible surgical devices. The STERIS® System utilizes a liquid chemical process (primarily buffered peracetic acid) for the rapid, low temperature, destruction of microorganisms on the surfaces of surgical instruments and devices. Please consult the STERIS® operator's manual for safe handling instructions for the STERIS® sterilant.

WARNING: Sterility of Karl Storz sheaths cannot be assured using the STERIS PROCESS™.

WARNING: During the STERIS® process failure to properly position telescopes so that all surfaces will be exposed to the sterilant or overloading the processing container may result in an ineffective sterile process and/or damage to the devices.

WARNING: During STERIS® sterilization processing only use STERIS® recommended containers to ensure proper sterilization of the telescopes.

WARNING: DO NOT use the STERIS® system for telescopes that cannot be immersed in liquid.

WARNING: Always verify that the sterilant container is empty after the cycle is complete. If the sterilant container is NOT empty, then the load CANNOT be considered sterile.

Sterilization Instructions for HOPKINSII® Rigid Telescopes and Miniature Semi-Rigid Telescopes (continued)

1). Be sure that all fetoscopy instruments are completely clean using the methods described in the appropriate cleaning section of this manual.
2). Visually inspect and test the instrument to ensure that it is working properly before processing in the STERIS processor.
3). Position the Instrument in the STERIS® tray to ensure that all surfaces will be exposed to the sterilant. All light cable adapters should be removed from the light post before processing.
4). Please consult the STERIS® operator's manual for more detailed instruction for use of the STERIS® processor.
5). The instruments are ready to use immediately at the completion of the STERIS® cycle.
6). Contact STERIS® Corporation for the most current STERIS® System processing options.

Sterilization Instructions for HOPKINSII® Rigid Telescopes, Miniature Semi-Rigid Telescopes and Sheaths

Sterilization using STEAM

WARNING: ONLY KARL STORZ TELESCOPES marked "AUTOCLAV" can be steam sterilized. Telescopes may only be sterilized in a pre-vacuum steam cycle.

PRECAUTION: Never attempt to cool telescopes by pouring cool, sterile liquid over the telescope. Forced cooling will cause severe damage to the telescope.

Sterilization Instructions for HOPKINSII® Rigid Telescopes, Miniature Semi-Rigid Telescopes and Sheaths (continued)

Sudden changes in temperature may fracture the glass components of telescopes. Do not immediately expose telescopes to air after removal from the autoclave.

1). Place the telescopes marked "autoclav" in a sterilization tray. Place instruments in a separate sterilization tray.
2). Karl Storz has validated the following steam sterilization parameters:

• **Pre-vacuum:**
Pre-vacuum or high vacuum sterilization consists of four basic phases: a conditioning phase, an exposure phase, an exhaust phase and a drying phase. The conditioning phase removes air from the chamber by pulling a vacuum and then warms the instruments by injecting steam. Sterilization occurs during the exposure phase when the chamber reaches a temperature of 270°F and pressure of 27 psi. The exposure phase in a pre-vacuum type of sterilizer is 4.0 minutes. The exhaust phase removes the steam from the chamber. The drying phase is accomplished by pulling an additional vacuum and allowing the instruments to dry under vacuum for approximately 20 minutes. The following conditions have been used to validate sterilization procedures in a pre-vacuum sterilizer:

Temperature: 270 to 272°F
Pressure: 27 psi
Exposure Time: at least 4 minutes for all instruments and telescopes

Sterilization Instructions for HOPKINSII® Rigid Telescopes, Miniature Semi-Rigid Telescopes and Sheaths (continued)

Gravity Displacement:
Gravity displacement sterilization also consists of four basic phases which are similar to the pre-vacuum type of sterilization. During the conditioning phase, steam is injected into the chamber and the air is forced out through the drain. Sterilization occurs when the temperature in the chamber reaches 250 to 254°F and the pressure reaches 15 psi. The exposure time for a gravity displacement sterilizer is longer than in a pre-vacuum sterilizer. The steam is removed from the chamber during the exhaust phase by allowing the steam to escape down the drain. The sterilized items remain in the chamber at atmospheric pressure to dry by the heat given off by the autoclave jacket. Karl Storz has validated the following sterilization conditions in a gravity displacement sterilizer for instruments:

Temperature: 250 to 254°F (121 to 123 °C)
Pressure: 15 psi
Exposure Time: at least 45 minutes

Flash Sterilization:
Flash sterilization can be accomplished in either a pre-vacuum or gravity displacement type of sterilization unit. Flash sterilization in a pre-vacuum unit proceeds without a conditioning phase or a drying phase. Flash sterilization in a gravity displacement unit proceeds without a drying phase. Karl Storz has validated flash sterilization using both a gravity displacement unit and pre-vacuum unit. The instruments must be disassembled. Flash sterilization of telescopes is not recommended. The following conditions were validated:

Gravity:
Temperature: 270 to 272°F (132 to 133°C)
Pressure: 27 psi
Exposure Time: 10 minutes for instruments

Prevacuum:
Temperature: 270 to 272°F (132 to 133°C)
Pressure: 27 psi
Exposure Time: 4 minutes for instruments

Sterilization Instructions for HOPKINSII® Rigid Telescopes, Miniature Semi-Rigid Telescopes and Sheaths (continued)

3). Trays should be positioned in the sterilizer so that there is adequate circulation and penetration of steam, air removal and condensate drainage. A loosely loaded sterilizer allows the best penetration of sterilant.
4). At the completion of the steam sterilization cycle, all instruments should remain untouched until adequately cooled.

References for Cleaning and Sterilization

1. Gruendemann, B.J. and Meeker, M.H. Alexander's Care of the Patient in Surgery, 7th edition. The C.V. Mosby Company, St. Louis, Mo. 1983.
2. Association for the Advancement of Medical Instrumentation. Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers. AAMI TIR No. 12-1994.
3. The Difficulty of Reprocessing Reusable Rigid Laparoscopic Forceps and Other Endoscopic Accessories: Are Disposables the Answer? Health Devices, Vol. 23, Nos. 1-2, pp. 57-58, 1994.
4. Descoteaux, J-G, Poulin, E.C., Julein, M. and Guidoin, R. Residual Organic Debris on Processed Surgical Instruments. AORN Journal Vol. 62, No. 1, pp. 23 - 29, 1995.

Quick Reference for Sterilization of Karl Storz Telescopes and Sheaths:

Sterilization Method	HOPKINSII® Rigid Telescope	Semi-rigid Telescope	Sheaths
Steam	Yes*	Yes*	Yes
STERRAD® System	Yes	Yes	Yes
STERIS	Yes	Yes	No

*Telescopes may only be sterilized in a pre-vacuum cycle.

WARRANTY POLICY

Except as otherwise provided herein and/or by the applicable warranty information for a specific product or type of product, all Karl Storz-branded products are generally warranted to be in good working order at the date of delivery and free from defects in workmanship and materials, for one (1) year from date of delivery. However, since some products carry a shorter or a longer warranty period, Customer should check with Customer Support or all product specific literature, instruction manual and/or labeling for the exact warranty period. Any such product(s) with a defect occurring during the applicable warranty period will be promptly replaced or, at the sole discretion of KSEA, repaired at no charge to Customer. **THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED AND/OR STATUTORY, INCLUDING, BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS AND/OR OF SUITABILITY FOR A PARTICULAR PURPOSE, WITH RESPECT TO ALL KARL STORZ PRODUCTS OR SERVICES, INCLUDING ANY PATENTS OR TECHNOLOGY RELATIVE THERETO. ANY AND ALL OTHER WARRANTIES, REPRESENTATIONS AND/OR GUARANTEES, OF ANY TYPE, NATURE OR EXTENT, BE IT IMPLIED, EXPRESS AND/OR WHETHER ARISING UNDER OR AS A RESULT OF ANY STATUTE, LAW, COMMERCIAL USAGE, CUSTOM, TRADE OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED AND DISCLAIMED.** Any contrary course of performance by and between the parties will not modify any representations and/or warranties set forth in the within Terms and Conditions. KSEA neither assumes nor authorizes any person to assume for it any other liabilities in conjunction with and/or related to the sale and/or use of its products. To ensure proper use, handling and care of Karl Storz products, Customer should consult the product specific literature, instruction manual, and/or labeling included with the product or otherwise available. Repairs, modifications or alterations of Karl Storz products, performed by any person or entity, other than by KSEA or an authorized repair facility of KSEA, nullifies and otherwise voids all applicable Karl Storz warranties. Repair or replacement of a Karl Storz product shall not extend the term of any applicable warranty. The remedies provided in the within Terms and Conditions are Customer's exclusive remedies under this Warranty Policy.

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Appendix I
KSEA Cleaning Accessories

Cleaning Brushes:

27648 A	Cleaning brush. Length: 50 cm
27650 A	Same, Length: 35 cm. Large size
27662	Grasping forceps for careful handling of instruments

Metal Sterilizing Cases:

27640 A	Metal case with cover for telescopes with holes for sterilization, 400 x 75 x 50 mm
27640 B	Same, 260 x 75 x 50 mm
27640 C	Same, 615 x 75 x 50 mm
27641 A	Same, 640 x 140 x 50 mm
27641 C	Same, 500 x 200 x 50 mm
27641 E	Same, 400 x 150 x 50 mm

Protective tubes for HOPKINS® telescopes:

723750 A	Length, 11.9 cm
723750 B	Length, 19.7 cm
723750 E	Length, 31.9 cm
723750 H	Length, 46.8 cm

Cleaning pistol and attachments:
27660

Appendix II

The following publications (1-21) address Selective Laser Photocoagulation (S-LPC) and amnioreduction:

1. Allen MH, Garabelis NS, Bornick PW, Quintero RA. Minimally invasive treatment of twin-to-twin transfusion syndrome. AORN J. 2000 Apr;71(4):796, 801-10; quiz 811-2, 815-8.

2. Cooper R, Bornick PW, Allen M, Quintero R. Endoscopic documentation of unintentional perforation of the dividing membrane during amnioreduction for twin-twin transfusion syndrome. Fetal Diagn Ther. 2001 Mar-Apr;16(2):101-4.

3. Crombleholme TM. The treatment of twin-twin transfusion syndrome. Semin Pediatr Surg. 2003 Aug;12(3):175-81.

4. Deprest J, Van Schoubroeck D, Lewi L, Marcus M, Jani J, Missant C, Devlieger R, Teunkens A, Vandevelde M. Randomized double blind comparison of remifentanil and diazepam for fetal immobilization and maternal sedation during fetoscopic surgery. American Journal of Obstetrics and Gynecology. 2004; 191 (6): S169.

5. Fieni S, Gramellini D, Piantelli G, Verrotti C, Cavallotti D. Twin-twin transfusion syndrome: a review of treatment option. Acta Biomed Ateneo Parmense. 2004;75 Suppl 1:34-9.

6. Fox C, Kilby MD, Khan KS. Contemporary treatments for twin-twin transfusion syndrome. Obstet Gynecol. 2005 Jun;105(6):1469-77.

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Patient Labeling

Patient Information

Selective Laser Photocoagulation for Treatment of Twin-to-Twin Transfusion Syndrome

Use of KARL STORZ Fetoscopy Instrument Sets

This patient information brochure is intended to provide general information to the patient.

The patient should discuss all the risks and benefits with her physician.

Table of Contents

What is TTTS?

Twins can be either "fraternal" or "identical." With fraternal twins, each baby has his or her own placenta and amniotic sac (bag of waters) in which they grow. Identical twins (also known as monochorionic twins) are different in that they grow in the same placenta. Each identical twin may have its own amniotic sac (diamniotic) or the twins may grow in the same placenta (the organ that exchanges blood between the mother and fetuses) and the same sac (monoamniotic). Twin-to-twin transfusion syndrome (TTTS) only occurs in identical twins who share the same placenta. With TTTS, there is an uneven flow of blood between the two babies through blood vessels that are present in the common placenta, resulting in a larger baby and a smaller baby. The larger baby (recipient) who has gotten too much blood develops an excessive amount of amniotic fluid (polyhydramnios). The smaller baby (donor) who has not gotten enough blood does not produce enough amniotic fluid (oligohydramnios) and appears to be stuck against the wall of the womb.

Figure 1: Graphic Representation of TTTS

TTTS occurs in 10-15% of identical twin pregnancies for unknown reasons. If the condition is left untreated, the pregnancy may be lost from too much stress on the heart in the larger twin, lack of enough blood getting to the smaller twin, or contractions that may cause miscarriage or premature delivery.

A five stage classification system of TTTS has been developed which helps the doctor to describe and categorize the status of the pregnancy. The classification includes stages I, II, III, IV and V. Stage I includes the initial symptoms of TTTS and can progress to Stage V which includes the most severe symptoms.

How is TTTS Diagnosed?

TTTS is diagnosed through an ultrasound evaluation as seen in Figure 2A (takes pictures of the babies by using sound waves and recording the echoes) and endoscope evaluation as seen in Figure 2B. The ultrasound is shown on the mother's belly.

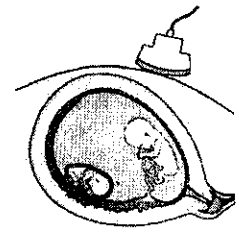

Figure 2A: Ultrasound evaluation

For a diagnosis of TTTS to be made, the ultrasound should show an excessive amount of amniotic fluid in the recipient twin and a lack of amniotic fluid in the donor twin. The ultrasound also confirms if the twins are in one placenta (monochorionic) or two sacs (diamniotic). Also shown in the picture is the fetoscope which is used to view the placenta as described in the section below.

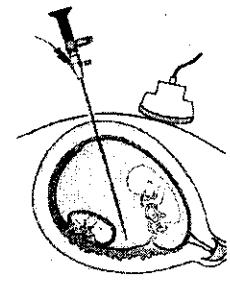

Figure 2B: Endoscope evaluation

What is S-LPC?

Selective laser photocoagulation (S-LPC) is used to treat TTTS by separating the circulation between the babies. The goal of the procedure is to use laser energy to block or seal off only the communicating vessels connecting the two babies so that they no longer share blood. This is done using a device called a fetoscope, which is a medical telescope, inserted through the mother's belly and amniotic sac. There are other blood vessels in the placenta that do not allow sharing of blood between the twins and the doctor works to avoid touching them. Only the vessels connecting the two babies are touched because the others bring nourishment to areas of the placenta that belong to each baby. See graphic representation of placenta before separation of the communicating vessels (Figure 3A) and after surgery (Figure 3B).

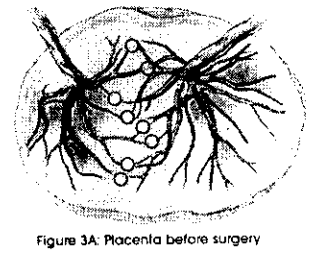

Figure 3A: Placenta before surgery

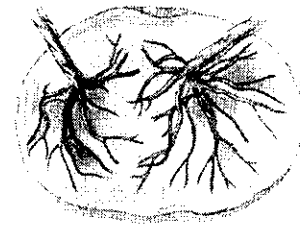

Figure 3B: Placenta after surgery

What are the Situations for Laser Treatment of TTTS?

Are you a candidate for this procedure?

- Is the gestational age of your babies more than 16 weeks and less than 26 weeks?
- Has a diagnosis of TTTS been made by your doctor?

You should not have this procedure if you have:

- Abnormal genetic studies
- A hole that has intentionally been made in the dividing membrane separating the babies (septostomy)
- Leakage of amniotic fluid from the vagina (ruptured membranes)
- Infection in the uterus (chorioamnionitis)
- Evidence of brain damage of either baby seen on ultrasound
- Separation of the placenta from the uterus (placental abruption)
- Active labor

Preparing for Surgery

You are not allowed to eat or drink anything 6 - 8 hours before surgery. This is necessary to prevent vomiting during surgery. In medical terms, this is known as "NPO" (nothing by mouth).

Before Surgery

In most cases you will be admitted to the hospital as an outpatient. Prior to surgery you will most likely be given an intravenous line (IV) in order to administer fluids and medication during surgery. Once prepared for surgery, you will be taken to the operating room and an ultrasound will be done before the procedure to confirm the babies' heartbeats.

How is S-LPC Performed?

Normally, the procedure is performed under intravenous (IV) (injection into the vein) sedation and local anesthesia (medicine to numb the surgical area). General anesthesia (medicine delivered through an IV and breathing equipment which makes the patient very sedated or unconscious) or epidural anesthesia (medicine delivered to the spinal column in which the patient is still awake) may be used under certain circumstances. There are cases in which the babies may still be able to move even with local or epidural anesthesia. In these situations, a muscle-blocking drug is injected into the thigh of the recipient twin with a very thin needle. This is done under ultrasound guidance and keeps the baby from moving in order to perform the surgery.

Procedure

After local anesthesia is provided, a small 2-3 mm (1/10") skin incision is made on your abdomen (belly) and a trocar (narrow metal tube) is inserted into the amniotic sac of the recipient twin. The pressure in the amniotic cavity may be monitored using a special gauge attached to the trocar. An endoscope or fetoscope (medical telescope) inside a protective operating tube, is passed through the trocar to observe the blood vessels on the surface of the placenta (see Figure 4).

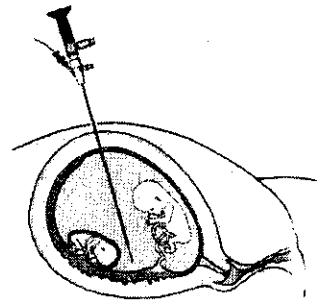

Figure 4: Inserting the fetoscope

An examination will identify the blood vessels that link the circulations between the twins. Only these blood vessels will be sealed off (photocoagulated) using laser energy. The laser will emit short pulses of energy lasting about 3 to 4 seconds for each blood vessel. The laser will be used repeatedly to seal off all of the identified blood vessels. In very few cases, a second trocar may need to be inserted, especially if the placenta is in the front of the uterus (anteriorly located).

Excess amniotic fluid may be removed from the recipient twin at the end of surgery. Antibiotics will be provided before and after surgery to prevent infection.

What Can Be Expected After Surgery?

You can expect to remain in the hospital for 1-2 days after surgery. The day after surgery, you will have an ultrasound examination to look at the condition of the babies. For at least the next four weeks after surgery, you will be asked to return to your doctor (obstetrician or perinatologist) for weekly ultrasounds. Your specialist will continue to monitor the condition of you and your babies.

Possible Benefits of the Surgery

Treatment of TTTS with laser therapy may benefit you by increasing the length of the pregnancy and the odds of survival of one or both babies. A clinical study in Europe called the "Eurofetus Study" was done to see how effective Selective Laser Photocoagulation (S-LPC) is in treating TTTS. They compared this treatment to amnioreduction which is another type of treatment available for TTTS. Over 100 pregnant women with twins suffering from TTTS participated in the study. About half of the women were treated with laser therapy and the other half were treated with serial amniodrainage. For women treated with laser therapy, more of the babies were still alive after 6 months of age and had less neurological damage (brain injury that may result in developmental delay or disability.)

Current findings indicate that there is a 76% chance of at least one baby surviving to 6 months of age (36% of both babies survive, plus a 40% chance of one survivor). In 24% of the cases, neither of the babies survive. A significant benefit of laser surgery is that it can cure TTTS by targeting the underlying cause of the condition. Another benefit may be a lower chance of one or both babies developing neurologic (brain) or cardiac (heart) complications.

These rates can be compared to other surgical procedures, (such as serial amniodrainage, septostomy and umbilical cord occlusion) which also can increase survival rates. Amnioreduction carries a 51% survival rate (for at least one twin surviving to 6 months of age) Septostomy may have a 70% survival rate for one twin (based on limited published information) and umbilical cord occlusion a 76% overall survival rate (this procedure results in the death of the donor twin and is associated with higher rates of brain or heart abnormalities in the surviving twin).

The average gestational age at delivery for the Selective Laser Photocoagulation (S-LPC) survivors was 33.3 weeks compared to 29 weeks for serial amniodrainage infants. The mean gestational age for septostomy was 30.7 weeks in a recent study. The gestational age is directly related to the prognosis of the infants. The prognosis improves as the gestational age increases.

What are the Possible Complications of the Surgery?

What are the risks to me?

The Eurofetus study also looked at problems that occurred to the mother, fetuses and infants following S-LPC and serial amniodrainage. The risk of a problem such as miscarriage or death of a fetus still inside the uterus within 7 days of the procedure was slightly higher for women who had S-LPC compared to women who had serial amniodrainage.

Procedure Risks:

Preterm Labor and Delivery:

Surgical procedures involving the pregnant uterus can result in uterine contractions and possible preterm labor. If labor cannot be stopped, the infant(s) may be born and suffer from complications of prematurity. (See section on prematurity on the next page.)

Wound infection:

May occur at the site where the trocar (narrow tube) is inserted into the abdomen for laser surgery. Wound infection is rare and occurs in less than 1% of surgeries in pregnant women.

Chorioamnionitis:

An infection of the membranes of the uterus and is a risk in any procedure in which it is necessary to enter the amniotic sac. This complication has happened after premature rupture of the membranes but is not a direct result of laser surgery.

Chorioamniotic separation:

May occur if the amniotic sac, containing the amniotic fluid and the baby, separates from the surrounding layer within the uterus called the chorion. This can lead to amniotic fluid leakage, premature rupture of the membranes and chorioamnionitis. This complication occurs in less than 5% of cases.

Amniotic fluid leakage:

Occurs rarely after a fetoscopic laser procedure but can lead to premature labor and delivery, premature membrane rupture, infection of the membranes or loss of fluid around the baby. If this occurs, you may need to remain in the hospital.

Amniotic fluid embolism:

In extremely rare cases, amniotic fluid may leak into the mother's bloodstream causing an embolism and is a risk in any procedure requiring access to the amniotic sac. The fluid can cause an allergic reaction (oversensitivity) with a sudden collapse of heart and lung function that can lead to death of the mother.

Placental abruption:
The placenta may separate from the uterus in this rare but serious complication. In the event that this occurs, an incision would be made into your uterus to deliver the babies by hysterotomy (cesarean section).

Bleeding/hemorrhage:
Can occur during the procedure from the uterine wall. If this occurs, the surgery may not continue. Bleeding may occur after a trocar is removed, however, this is controlled by placing external pressure on the surgical site. In the event that bleeding does not stop, it may be necessary to place stitches on the wall of the uterus.

Complications from severe bleeding:
Bleeding of a significant degree may occur requiring that you receive blood through a blood transfusion. In addition, although rare, there may a large amount of bleeding that may require the removal of your uterus (hysterectomy). This would not allow you to have any more children. Damage to many of your organs, brain damage, or death could result from severe bleeding.

Inability to have future children:
This occurs very rarely, and even at a lower rate than with a Cesarean delivery.

Hysterectomy:
Removal of the uterus.

Maternal death:
Is an extremely rare occurrence that is primarily caused by one or more of the listed complications of surgery.

Anesthesia Risks:

Epidural anesthesia:
Spinal headache, failure of anesthesia to prevent sensation, infection, blood clot, brain injury, drug side effects such as itching, nausea, vomiting, inability to urinate, abnormal breathing, seizure, and low blood pressure.

General anesthesia:
Nausea, vomiting, inhaling mucous into the lungs (aspiration), inability to breathe with a mask, or inability to place a breathing tube in the windpipe.

What are the Risks to my Baby?

Chorioamniotic separation:
May occur if the amniotic sac, containing the amniotic fluid and the baby, separates from the surrounding layer within the uterus called the chorion. The possible outcomes of chorioamniotic separation include: premature rupture of the membranes, entanglement of fetal arms, legs, face or umbilical cord in amniotic banding, called amniotic band syndrome, or uterine or vaginal bleeding resulting in fetal separation or death.[10]

Neurological complications or other forms of brain damage may occur.
This complication may be present before surgery, after surgery, or develop after birth. This can include problems with movement, brain development or vision development.

Complications of prematurity:
All babies with TTTS deliver prematurely, usually between 31 and 33 weeks gestation. The laser procedure could potentially result in more babies living but still being born prematurely. Complications of prematurity include bleeding in the brain (intraventricular hemorrhage), abnormalities of the eye which can affect vision (retinopathy of prematurity), infection in the blood, a severe infection of the intestines (necrotizing enterocolitis), and death.

Fetal injury during entry to the placenta by instruments.

Morbidity after birth:
Babies born with TTTS may have moderate to severe problems, including severe respiratory failure, forgetting to breathe (apnea), slow heart rate (bradycardia), low urine output (renal insufficiency), high blood pressure, failure to thrive, and complications of prematurity.

Incomplete separation of fetal circulation:
Incomplete separation of connections between the two babies.

Subchorionic hematoma:
Rarely, there is bleeding into the placenta immediately below the vessels being sealed.

Fetal death - intrauterine or neonatal:
Fetal death because of the laser procedure is rare. Cutting (laserating) instead of photocoagulating the placental vessels can occur in a large vessel which may result in fetal bleeding leading to death. Premature labor and delivery may also result in fetal death.

Other Complications:
In rare cases there may be other complications that affect development of fetal organs such as bowel, arm/legs or skin.

What is the Risk of Fetal Death?

After laser surgery, sometimes one baby may die. The death of one or both of the babies can occur anytime from the time of surgery until delivery. This may happen because the babies are unhealthy due to TTTS, other conditions or possibly because of inadequate placenta share. An estimate of how much each baby has or will have after surgery cannot be made at the time of surgery. However, if one of the babies dies, the other baby should not be affected or since they will no longer be sharing placenta.

What are the Treatment Alternatives to Laser Surgery for Twin-to-Twin Transfusion Syndrome?

No intervention:

This allows nature to take its course. The pregnancy will be monitored with ultrasound examinations. Medications may be offered to reduce the recipient twin's urinary output to decrease excess amniotic fluid, or assist both fetuses' hearts. You should know that this option has not been successful in treating TTTS and results in the loss of the pregnancy in 95% of the cases.

Serial Amniodrainage:

In serial amniodrainage, extra fluid is removed from the amniotic sac of the recipient (larger) twin with a needle. This procedure may need to be repeated several times and is done to reduce the pressure in the uterus. Each time fluid is removed, 1-3 liters may be obtained. There is approximately a 56% survival rate of at least one twin to 28 days of age.

Selective feticide:

In this procedure, blood flow to one twin is interrupted by umbilical cord occlusion (closing off), ligation, or coagulation (blocking off). This fetus dies and remains in the uterus for the remainder of the pregnancy with the other twin, who should not be affected by the death of the first twin. The surviving twin may face developmental problem throughout his/her life. There is approximately a 36% survival rate of at least one twin. This rate includes the expected loss of one twin. This procedure is usually recommended only when it is the only alternative for improving the chance that at least one twin will survive.

Fetal Septostomy:

This procedure creates intentional holes in the dividing membrane between the twins using a thin needle. The result should cause fluid to move from recipient's sac to the donor's sac, creating a false but equal balance of fluid volume between the two sacs. Septostomy does not cure TTTS and may cause premature labor, placental abruption or fetal death from cord entanglement. Based on limited published information, there is approximately a 70% survival rate of at least one twin.

Termination of the pregnancy:

This option may be chosen any time up to 24 weeks of gestation.

[illegible] Selective feticide in [illegible] monochorionic twin pregnancies by [illegible] cord coagulation [illegible] Obstet Gynecol. 2003 Nov [illegible] 484-8
[illegible] Twin to twin transfusion syndrome: treatment by amniodrainage and septostomy. Eur J Obstet Gynecol Reprod Biol. 2000 Sep [illegible]
[illegible] Amniotic Fluid Pressure in Both Cavities of Twin to Twin Transfusion Syndrome [illegible] against Septostomy. Fetal Diagn Ther 2000 [illegible]
[illegible] Failure of Amniotic Septostomy in the Management of [illegible] Fetal Diagn Ther [illegible]
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Glossary

Allergic Reaction
The body's way of responding to an unknown substance, such as dust, pollen, medications. Some reactions could be in one spot such as itchy eyes, or all over the body, as in a rash.

Amniodrainage
Removal of extra fluid from the amniotic sac of the recipient twin.

Amniotic Fluid
Waters surrounding the unborn baby.

Amniotic Sac
A bag of tissue that surrounds the unborn baby and holds the amniotic fluid.

Anesthesia
A drug which causes loss of sensation or feeling.

Anteriorly Located
In front of uterus.

Antibiotics
Drugs used to stop or slow down the growth of germs.

Bladder
A hollow organ in the lower belly that stores urine (pale yellow liquid waste material).

Cesarean Delivery
A surgical procedure to remove the baby from the uterus of a pregnant woman who is near full term.

Cardiac cycle
Pertaining to the heart.

Cardiac overload
Stress on the heart.

Catheter
A flexible, tube-like tool used to take fluids out or put fluids into the body.

Chorioamnionitis
Swelling of the tissue that covers the unborn baby.

Chorion
The outside layer of tissue that covers the unborn baby.

Circulation
The movement of blood around the body to arteries and veins.

Diamniotic Twin
An identical twin with its own amniotic sac.

Donor
The smaller baby who is stuck against the uterine wall, has very little amniotic fluid, and does not receive enough blood.

Embolism
Blood clot

Epidural anesthesia
A numbing drug which is injected into the spine to numb the lower abdomen, pelvis, and legs.

Feticide
Intentional abortion of an unborn baby.

Fetoscope
A medical telescope inserted through the mother's belly and amniotic sac to view the babies.

Fetus
An unborn baby from 9 weeks after it is formed until it is born.

Fraternal
Twins with separate placenta and amniotic sacs (bags of tissue).

General Anesthesia
A drug or agent used to decrease the feeling or pain of a patient, thus making pain by putting you to sleep.

Gestation
Period of time from baby formation until it is born.

Gestational Age
The age of the baby in weeks from formation until before it is born.

Hysterectomy
A surgical procedure to remove the uterus.

Hysterotomy
A surgical procedure to remove the baby from the uterus of a pregnant woman who is near full term (as in Cesarean section)

Infection
The invasion of the body by germs and bacteria that can multiply and lead to tissue damage and disease.

Intrauterine
Inside the womb.

Intravenous
Injection into the vein

Local Anesthetic
A drug or agent used to decrease the feeling of pain by numbing an area of your body, without putting you to sleep

Membrane
A thin layer of tissue covering a surface.

Monoamniotic
Identical twins that grow in the same placenta and the same amniotic sac.

Monochorionic
Identical twins that grow in the same placenta

Morbidity
Illness, disease

Neonatal
Period of time that is 4 weeks after birth

Neonatologist
A doctor who takes care of high risk babies during the newborn period, which is 4 weeks after birth.

Obstetrician
A doctor who takes care of pregnant women or delivers babies.

Oligohydramnios
A condition in which there is very little or a lack of amniotic fluid, typical of the donor twin.

Perinatologist
A doctor who takes care of high-risk pregnant women and babies during the prenatal period, which starts about 20 weeks before birth and can extend up to 4 weeks after birth.

Photocoagulate
To seal off using laser energy

Placenta
Tissues that provide food for the unborn baby

Placental Abruption
Separation of the placenta from the uterus

Polyhydramnios
A condition in which there is excessive amount of amniotic fluid, typical of the recipient twin.

Posteriorly Located
Behind the uterus.

Premature Delivery
Delivery that takes place before 37 weeks of gestation has passed

Prematurity
Baby born before 37 weeks of gestation has passed, counting from the first day of the last menstrual period.

Recipient
The larger baby who has too much amniotic fluid and gets too much blood.

Septostomy
A procedure in which a needle is used to make a hole in the dividing membrane to separate the babies.

Sheath
A protective covering.

S-LPC
Selective Laser Photocoagulation- separates circulation between the babies

Trocar
A narrow metal tube.

TTTS
Twin-to-twin transfusion syndrome.

Ultrasound
A device that takes pictures of the babies by using sound waves and recording the echoes.

Umbilical Cord
The cord that connects the developing baby with the placenta.

Uterine Wall
The wall of the uterus consists of the outer tissue that covers the uterus, smooth muscle that contracts for labor and delivery, and the tissue lining the uterus that becomes the placenta.

Uterus
The womb located in a woman's lower abdomen.

Vessels
A tube, duct or canal to transport the fluids of the body.