

Instructions for Use

Elana Surgical Kit Humanitarian Use Device

Elana Catheter 2.0
Elana Rings 2.6 & 2.8
Medela Tubing



1. Description

The ELANA (Excimer Laser Assisted Nonocclusive Anastomosis) operating technique was developed by neurosurgeon C.A.F. Tulleken in 1993. It should be used only if a bypass to or from the chosen vessel is indicated and the surgeon considers the vessel adequate to receive a large caliber anastomosis.

For the steps of preparing and creating the arteriotomy, the ELANA operating technique requires two devices: the Elana Catheter 2.0 and either one of the Elana Rings 2.6 & 2.8. These devices are jointly called Elana Arteriotomy System[®] and are included in the Elana Surgical Kit[®] together with the Medela Tubing

The Elana Surgical Kit[®] does not create an anastomosis or bypass, it merely replaces the tools used to make a conventional arteriotomy. The arteriotomy site must be prepared with microsurgery techniques using an Elana Ring before the arteriotomy is made with the Elana Catheter.

The Elana Rings 2.6 & 2.8 are made of platinum, have a inner diameter of 2.6 mm and 2.8 mm and a material thickness of 0.25 mm. The Elana Rings 2.6 & 2.8 were determined to be MR safe.

The Elana Catheter 2.0 is a laser - vacuum suction Catheter consisting of a multitude of silica glass fibers suitable for the transmission of ultraviolet light arranged to form a plane circle with an outer diameter of 2.0 mm at the tip. Inside this circle ends a vacuum lumen in a grid. The grid and its holder as well as centering ring on the outside of the Catheter near

the tip are made from stainless steel. Apart from this, the Catheter and the lumen consist of plastic material. The Catheter has a female luer lock connector for the connection to a vacuum source and a connector for connection to an excimer laser system.

The Elana Rings 2.6 & 2.8 are designed to aid the surgeon in the preparation of a circular arteriotomy site. One Ring is to be connected to the recipient artery wall and the donor graft wall with conventional micro neurosurgery suturing techniques to prepare an end-to-side anastomosis on a nonoccluded recipient vessel.

The Elana Catheter 2.0 is designed to perform a circular arteriotomy in the wall of an artery while blood is flowing through the artery's lumen at a site that is prepared by the attachment of a graft and an Elana Ring 2.6 or 2.8. The Catheter is advanced through the donor graft, vacuum is applied to hold the wall and laser light is used to perform the arteriotomy. The diameter of the ring of fibers in tip of the Elana Catheter 2.0 is 2.0 mm. The arteriotomy will therefore have a diameter of 2 mm.

2. Intended Use / Indications for Use

The Elana Surgical Kit[®]UD, when connected to the Spectranetics Xenon-Chloride Laser Model CVX-300, is indicated for creating arteriotomies during an intracranial vascular bypass procedure in patients 13 years of age or older with an aneurysm or a skull base tumor affecting a large (> 2.5 mm), intracranial artery that failed balloon test occlusion, cannot be sacrificed, or cannot be treated with conventional means due to local anatomy or complexity.

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3. Contraindications for Use

- The Elana Surgical Kit[®]UD should not be used on graft vessels that show signs of arteriosclerosis or calcification.
- The Elana Surgical Kit[®]UD should not be used when flow in a recipient artery is interrupted or reduced.
- The Elana Surgical Kit[®]UD should not be used on a recipient artery whose lumen is constricted at the anastomosis site or during attachment of an Elana Ring.
- An Elana Surgical Kit[®]UD should not be used on a site where the catheter with donor graft is not perpendicularly accessible.
- The Elana Surgical Kit[®]UD should not be used on a recipient artery that has a wall thickness greater than that of a human internal carotid artery or identified to have an abnormality like an unusually high or low wall thickness, calcification, or detachable layers in the wall (which could cause the laser light to cut less effectively through the wall).
- The Elana Surgical Kit[®]UD should not be used on a recipient artery with a foreign material like stents or suture at or beneath the selected site. The arteriotomy may not be successful.
- The Elana Surgical Kit[®]UD should not be used on an aneurysm itself. Rupture of the aneurysm could result.
- The Elana Surgical Kit[®]UD should not be used when contact of the catheter tip with the recipient artery wall is hindered or made difficult by a thick donor graft wall or a small donor graft lumen.

4. Complications

Procedures requiring micro neurosurgery techniques and manipulation of intracerebral vessels and aneurysms, procedures requiring suction through vacuum aspiration and procedures requiring excimer laser ablation techniques should not be attempted by physicians unfamiliar with possible complications, which may occur during or after the procedure. Possible complications include, but are not limited to, the following: air embolism; infection; distal embolization; vessel spasm; thrombosis; dissection or perforation; acute or delayed occlusion; ischemia; bleeding; intracranial hemorrhage; anastomotic leakage; hydrocephalus; aneurysm or vessel rupture; false aneurysm formation; neurological deficits including stroke, and death.

5. Warnings and Precautions

- Store Elana Catheter and Elana Rings in a cool and dry place. Exposure to temperatures above 54°C (130°F) may damage the devices.
- Use Elana Catheter and Elana Rings by "Use By date".
- Sterility or functionality may be compromised.
- Before the surgery, ensure availability of the Elana Rings and the Elana Catheter with compatible extension line and adaptors with at least one completed spare set and check the functionality of the recommended suction and laser systems as per their instructions for use.
- Before use, visually inspect the sterile packages. Do not use open or damaged packages or packages with broken seals. Sterility or functionality of the devices may be compromised.

Handle the Elana Catheter and the Elana Rings with care; devices are easily damaged. Do not expose devices to solvents or bring in contact with powdered parts of surgical gloves.

Prior to use carefully examine the Elana Rings for defects and examine and test the Elana Catheter for defects and proper functioning. Do not use a device that shows signs of damage, deformation or malfunction, this may cause complications.

The Elana Ring must be a complete, unbroken circle, perfectly flat and of even thickness from the side, with a smooth and even surface.

The Elana Catheter: the outer jacket must not have bends or kinks or perforations. The luer-lock coupling must be firmly fixed in the bifurcation and must not be twisted. Examine the tip of the catheter under magnification while holding the fibers in the coupler in the direction of a conventional light source. At each position in the circle there must be at least one illuminated fiber. The tip must contain fibers arranged in a circle. There must be no two adjacent spaces without illuminated fibers. The grid inside the circle must have 19 individual, separated holes without obstructions or protrusions or particles inside the holes or on or above the grid. Partial occlusion of the holes in the tip or an imperfect circle of illuminated fibers or inability to conduct the correct amount of laser light may result in failure to fully perforate the recipient artery wall and/or failure to remove a cut-out disc and/or ensue wall damage.

Ensure the Elana Catheter is able to hold vacuum without leakage and able to conduct suction: with occluded tip, e.g. held against a soft, clean, unpowdered sterile surface such as a clean surgeon's glove, the catheter must be able to exert a small pulling force without breaking loose and the pressure reading must show the same maximum reading as when the vacuum source is operated with closed suction jar. When the vacuum source is deactivated by turning off the power while the catheter tip is occluded, the pressure reading must remain unchanged, showing the absence of leaks.

When releasing the tip from the obstruction, suction must be drawn through the catheter so that the pressure meter on the pump drops quickly to lower relative pressure, falling by about 50% within 15 seconds with a volume of 500ml in the suction jars. Only use a vacuum source delivering a vacuum of at least -90kPa / -675 mmHg. Leaks or occlusions in the system including any connections between the catheter and extension line or a lower vacuum may result in failure to fully perforate the recipient artery wall and/or failure to remove a cut-out disc.

Ensure the catheter can conduct 308nm laser energy at pulses of 10mJ at 40 Hz to the tip, do not use different laser energy.

Do not use more than one Elana Ring (either 2.6 or 2.8, not both) for an anastomosis.


Do not use the Elana Catheter or the Elana Rings endovascularly or without direct visual access.

Do not use an Elana Catheter twice, not even in the same surgery. Function may be impaired.

Do not re-sterilize or reuse! Structural integrity and/or function may be impaired by sterilization, prior use or

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- c) without unduly constricting the recipient's lumen and without obstructing the flow of blood, i.e. while blood is circulating through the recipient artery.
 - 5. Remove the loop the Elana Ring is provided on for handling and identification. The loop can be cut like conventional suture.
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- All operating room personnel within the nominal hazard zone should wear protective shielding against 308nm radiation when the laser is in use or during calibration as per the laser manufacturer's recommendation. Avoid eye or skin exposure to direct or scattered radiation. Only a microscope with a proper filter will provide adequate protection against direct or scattered light. Refer to the exposure label on the Laser System.
 - The use of the Elana Surgical Kit_{HD} does not require temporary occlusion of the artery. This may reduce time pressure experienced by the surgeon in conventional surgery. The use of the Elana Surgical Kit_{HD} also involves additional steps and would thus likely take longer than conventional surgery. Surgery time and anesthesia time will likely be longer.

6. Instructions for Use

Caution: the Elana Surgical Kit_{HD} is intended for use by qualified medical personnel trained in the use of the Elana Surgical Kit_{HD} and compatible equipment as well as in microsurgical suturing techniques and the treatment of complex lesions by creation of bypasses to major intracerebral arteries. Please observe the warnings and precautions above as well as the instructions for use of the compatible equipment used.

The Elana Surgical Kit_{HD} is used in the setting of vascular micro neurosurgery. Follow all general guidelines applicable to anesthesia, vascular neurosurgery, disinfection, working under sterile conditions and laser safety.

The following steps are recommended:

1. Prepare a suitable donor graft for the bypass and select proximal and distal bypass sites. Selection criteria are described in the steps below and in Section 3.
2. After surgical preparation of the recipient artery and removal of excessive extra-adventitial tissue from the anastomosis site, choose either an Elana Ring 2.6 or an Elana Ring 2.8 from a set of Elana Rings 2.6 & 2.8 depending on the diameter of the recipient artery and – if you intend to evert the graft over the Elana Ring – also depending on the wall thickness of the donor graft. The Catheter tip must be able to pass unhindered through the Elana Ring to the end of the graft, touching the recipient artery wall when the Ring is attached.
3. Handle and inspect the Elana Rings with care, see chapter 5.
4. Place the selected Elana Ring onto the recipient artery to confirm it can be attached
 - a) on a site perpendicularly accessible to the Elana Catheter 2.0;
 - b) on a healthy site without arteriosclerotic or calcified lesions or any wall abnormality, which could cause the laser light to cut less effectively through the wall (e.g. an unusually high wall thickness) and that is free of any foreign material like stenosis or suture at or beneath the selected site.

for use, keeping the distal part of the Elana Catheter sterile. The laser must be set to the fluence and frequency indicated on the label of the Elana Catheter 2.0. Upon successful calibration, a pulse energy of 10mJ will be temporarily displayed on the laser.

11. Fig. E: Insert the distal end of the Elana Catheter 2.0 into the donor graft through an arteriotomy on its side or an open end of the graft until its tip touches the artery wall inside the Elana Ring evenly and perpendicularly. Keeping the distance between the Catheter entry and the recipient small will facilitate correct positioning and fixation.

Caution: the vacuum suction must not be active before the Elana Catheter tip is in full, perpendicular contact with the recipient wall inside the graft.

Caution: the donor graft should not have valves between the entry site of the Elana Catheter 2.0 and the end connected to the recipient artery.

Caution: the openings inside the Elana Catheter tip may occlude if the Catheter is in contact with blood without active vacuum suction. Do not bring the Elana Catheter in contact with bodily fluids except to position it on the recipient wall inside the graft. Flush the graft with heparinized saline prior to entry of the Catheter and do not delay the activation of vacuum. The openings are too small to be safely cleaned. Do not reuse an Elana Catheter that had to be removed from the graft for any reason.

12. Apply suction by activating the vacuum source according to its instructions for use with maximum vacuum (same value should be displayed as with a sealed off pump without extension and catheter). The suction exerted by the vacuum on the recipient artery wall can be felt by briefly pulling slightly – ensure not to lift or move the artery unduly. For two (2) minutes the Catheter tip should be held in steady contact with the artery wall, neither pushing nor pulling nor tilting nor twisting nor moving. The vacuum pulls the artery wall and puts tension on it. For complete perforation it is important that this tension is even and drawn through the extension line. Ensure the vacuum suction remains active throughout all subsequent steps.

Caution: the Elana Catheter must not be pushed down on the artery as this might constrict the vessel lumen or occlude the artery, leading to ischemia. During lasing, pushing the Catheter may lead to severe vessel damage.

Caution: be careful not to twist or move the Elana Catheter while applying suction. Torque or movement thus transmitted to the recipient artery may prevent a good arteriotomy or in extreme cases may cause vessel damage. Ensure the remainder of the catheter is not moved and the position and orientation of the bifurcation remains steady until the catheter is removed from the graft. Hold the catheter steady to be able to prevent the transmission of accidental movements to the tip.

13. After the two minutes, activate the laser for 5 seconds at 40Hz, delivering a total of 200 pulses according to the laser's instructions for use.
 - a) The Elana Catheter is firmly held but neither pushed nor pulled nor moved during firing of the laser. The artery must not be deformed and its lumen must not be constricted, yet the Catheter must remain in contact

with the vessel wall. Be careful that the front and back wall of the artery do not approach or touch.

- b) When 200 pulses are delivered the laser will stop automatically and the footswitch of the laser must be released.

Caution: be careful not to release the footswitch of the laser before the 5 seconds of lasing are over and the laser system automatically stops operation.

14. Fig. F: After lasing, remove the Elana Catheter 2.0 carefully from the graft. Take care not to exert undue forces onto the artery or the graft or the sutured anastomosis. Set the laser system to standby to avoid accidental operation after a mandatory pause of the system of 10 seconds.

Note:

- Retrograde blood flow through the donor graft bears witness to the successful penetration of the artery wall by the laser light delivered through the Elana Catheter 2.0 and can be stopped by temporarily occluding the donor graft to allow completion of the bypass or closure of the arteriotomy in the graft. Be sure to adequately flush the donor graft with anticoagulants before opening the flow.
- The vacuum suction must remain active until the Elana Catheter 2.0 is fully removed from the blood to retrieve tissue cut out by the catheter. Retrograde blood should fill the graft in front of Elana Catheter tip and flush the graft from any debris and air. Should, however, no blood fill the graft (e.g. because of unidentified valves in the graft or if the arteriotomy was unsuccessful), the graft walls may be pressed against the Elana Catheter as a result of vacuum suction. Be careful not to damage the vessels or anastomosis when removing the catheter and ensure the graft is flushed out afterwards to remove any tissue or debris that may have been left in the vessel.
- Check if a circular tissue disc ("flap") cut out from the artery wall is still attached to the tip of the Catheter. If it was not retrieved with the Elana Catheter, the laser perforation may not have been fully successful for the entire circle, leaving a segment still attached to artery wall. This condition may occur if the Catheter does not fully or unevenly touch the artery wall within the Ring or if the suture exerts uneven or excessive tension on the artery wall within the Ring.

Warning: If the circular disk of tissue (or "flap") is not retrieved with the Elana Catheter, it is likely still attached to the artery wall and is considered a retained flap. When a retained flap exists, the surgeon should assess the flap and consideration should be given to its removal since there is a theoretical concern that a retained flap could embolize when not removed manually. The rate of flap retention in one clinical study was 22% (8/37 device uses in 33 subjects). In 5 of those 8 subjects with a retained flap, the flap was manually retrieved with 1 severe adverse event (a diffuse subarachnoid hemorrhage and thrombosis of basilar aneurysm with compression of the ventral pons) observed. In the 3 cases where no flap was retrieved. In the 5 cases where a flap was manually retrieved, there was 1 severe adverse event consisting of an aneurysm rupture due to manipulation / inspection of distal anastomosis and subsequent stroke.

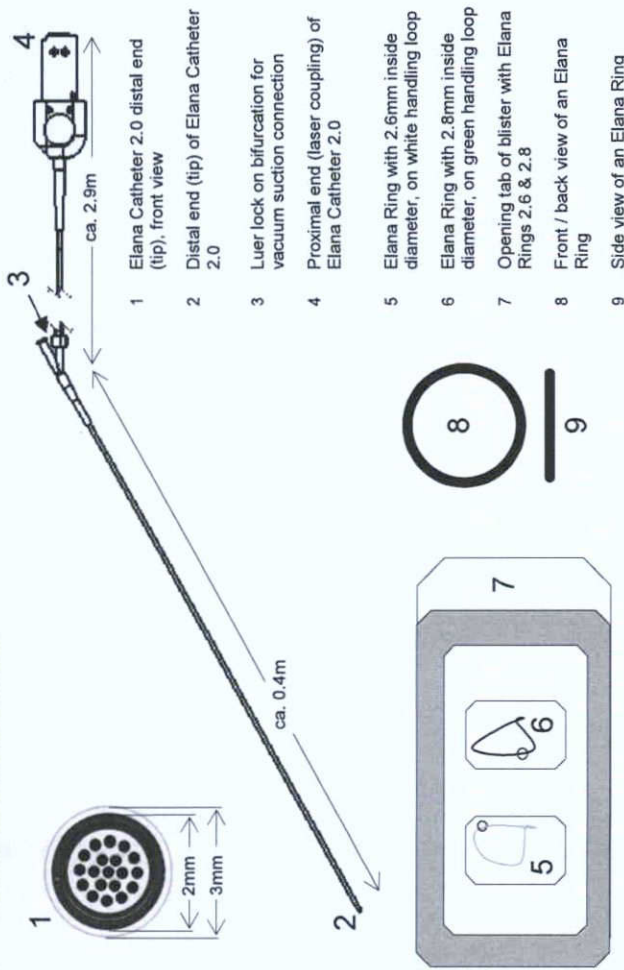
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One patient with a retained flap experienced an embolic stroke immediately post-procedure in a series of 330 European cases, and embolization of the retained flap could not be excluded

If the surgeon finds the flow through the bypass to be inadequate for the situation and if the flap can not be manually removed, the anastomosis should not be used and another anastomosis should be made to complete the bypass

7. Schematic and Explanation of Terms



8. MRI LABELING

MRI Information: The Elana Ring (platinum, 2.8-mm diameter) was determined to be MRI-Conditional based on the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2003 Non-clinical testing demonstrated that the Elana Ring is MRI-Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the Elana Ring produced a temperature rise of 0.3 °C at a maximum MR system-reported (i.e., displayed on the MR system console) whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite, Software G3.0-02B, General Electric Healthcare, Milwaukee, WI). MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Elana Ring. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary. The table provides a comparison between the signal void size and imaging pulse sequences at 3-Tesla.

Pulse Sequence	T1-SE		T2-SE		GRE	
	(long axis)	(short axis)	(long axis)	(short axis)	(long axis)	(short axis)
Signal Void Size	26mm	8mm	26mm	8mm	46mm	38mm
TR (msec)	200	200	200	200	15	15
TE (msec)	20	N/A	20	N/A	15	15
Flip Angle	N/A	N/A	N/A	N/A	15°	15°
Field of View	20 cm	20 cm	20 cm	20 cm	20 cm	20 cm
Section Thickness	5 mm	5 mm	5 mm	5 mm	5 mm	5 mm
Imaging Plane	Parallel (long axis)	Perpendicular (short axis)	Parallel (long axis)	Perpendicular (short axis)	Parallel (long axis)	Perpendicular (short axis)

9. Compatibility

The Elana Catheter 2.0 is compatible with the following:

Laser

- 308nm Medical Excimer Laser System able to:
 - accommodate the coupling piece of the Elana Catheter 2.0 homogeneously couple the laser energy into all of the fibers in the proximal fiber bundle of the Elana Catheter 2.0
 - measure the Catheter output pulse energy and set it to the desired value without impairing the function of any of the fibers of the Elana Catheter 2.0
 - allow the surgeon to control the delivery of a 5 second long pulse train of 200 pulses at 40 Hz, each pulse with a pulse duration of 125 – 200 ns and a pulse energy of 10mJ at the distal tip of the Elana Catheter 2.0
 - has a single fault condition safe mechanism ensuring the stability of the delivered energy

Caution: Do not use other lasers, damage to surrounding tissues, vessel damage, inability to perforate the vessel wall, embolization, thrombosis, coagulation, embolism, stroke or death may result.

Elana by recommends the use of the following laser system for use with the Elana Catheter 2.0:

Spectranetics CVX-300®

Manufacturer:
Spectranetics Corporation,
9965 Federal Drive
Colorado Springs, CO 80921-3617 USA

Model Number: CVX-300®
Also available via Elana by

Note: The CVX-300® Excimer Laser System should only be used by physicians who have received adequate training.

CVX-300® is a registered trademark of the Spectranetics Corporation.

Vacuum source

- A medical vacuum aspiration and suction system intended for vacuum aspiration and removal of surgical fluids and tissue from wounds during surgery
- able to deliver a maximum vacuum of at least 90kPa / -675 mmHg
- suction capacity of at least 10 l/min
- able to hold such vacuum in case of power loss for at least two minutes with less than 10% reduction in vacuum and able to be shut off and release the vacuum if intended
- able to connect with tight seals to the luer-lock connector of the vacuum system via an appropriate M/M extension line
- with sterilizable or disposable suction jar or container of 0.25l capacity and overflow protection device

Elana by recommends the use of the following vacuum source with the Elana Catheter 2.0:

Medela dominant 50 (mobile)

Manufacturer:
Medela AG, Medical Technology,
Lättlichstrasse 4b, CH-6341 Baar / Switzerland

Available from Elana by or Medela AG or their distributors and representatives (see www.medela.ch). Available in the USA from Medela, Inc., 1101 Corporate Dr. McHenry, IL 60050 USA
Art.-No. 057.0111 (240V/50Hz)
Art.-No. 057.0224 (120V/60Hz)















Vacuum extension line and adaptors


To connect the vacuum source to the female luer lock connection of the Elana Catheter 2.0, use a sterile medical extension line suitable for vacuum suction with least 1.5mm inner diameter and no more than 3m in length and adaptors as required, such as the Medela tubing which is enclosed in the Elana Surgical Kit. Ensure no leakage or occlusion occurs. Sterile connecting adaptors and extension lines are available e.g. from vacuum equipment manufacturers such as Medela AG and disposable equipment manufacturers.

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10. Symbols

-  Caution, consult accompanying documents
-  Do not reuse
-  Lot number
-  Catalogue number (Elana bv part number)
-  Sterilized with EtO (ethylene oxide)
-  Sterilized with gamma radiation
-  Nonpyrogenic
-  Use by
-  Manufacturer
-  Store in a cool dry place
-  Elana Ring with white suture loop has 2.6mm inner diameter;
Elana Ring with green suture loop has 2.8mm inner diameter.
-  MR conditional

11. Manufacturer and ordering information, availability

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Humanitarian Device.
 Authorized by Federal law the Elana Surgical Kijlpin, when connected to the Spectranetics Xenon-Chloride Laser Model CVX-300, is indicated for creating arteriotomies during an intracranial vascular bypass procedure in patients 13 years of age or older with an aneurysm or a skull base tumor affecting a large (> 2.5 mm), intracranial artery that failed balloon test occlusion, cannot be sacrificed, or cannot be treated with conventional means due to local anatomy or complexity.

The Elana Surgical Kijlpin contains the Elana Arteriotomy System which consists of the Elana Catheter 2.0 and the Elana Rings 2.6 & 2.8 and the Medela Tubing, is only available in the United States of America from the manufacturer of the Elana Surgical Kijl-Humanitarian Use Device, REF 801-H.

Elana bv