

519211

K061095
page 1 of 1

Auto Suture™ ENDO GIA™ Surgical Stapler

510(k) Summary of Safety and Effectiveness

SUBMITTER: United States Surgical, a division of Tyco Healthcare Group LP
150 Glover Avenue
Norwalk, CT 06856
Tel. No.: (203) 845-1000

MAY 3 1 2006

CONTACT PERSON: Frank Gianelli
Senior Associate, Regulatory Affairs

DATE PREPARED: April 17, 2006

TRADE/PROPRIETARY NAME: Auto Suture™ ENDO GIA™ Stapler

COMMON/USUAL NAME: Staple, Implantable

CLASSIFICATION NAME: Staple, Implantable

PREDICATE DEVICE(S): Auto Suture™ ENDO GIA™ Stapler

DEVICE DESCRIPTION: The Auto Suture™ ENDO GIA™ Stapler places two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows. The size of the staples is determined by the selection of the 2.0 mm, 2.5 mm, 3.5 mm or 4.8 mm single-use loading unit (SULU). The ENDO GIA™ Stapler will accommodate any of the single-use loading units that are available in 30 mm, 45 mm and 60 mm sizes.

INTENDED USE: The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

TECHNOLOGICAL CHARACTERISTICS: The Auto Suture™ ENDO GIA™ Stapler is identical to the predicate device. The only change is the inclusion of a specific indication concerning the device's use on liver tissue as a subset of the general indication for the Auto Suture™ ENDO GIA™ Stapler.

MATERIALS: All components of the Auto Suture™ ENDO GIA™ Stapler are comprised of materials which are in accordance with ISO Standard 10993-1.

PERFORMANCE DATA: In-vivo animal tests were performed to support the inclusion of a specific indication as a subset of the general indication for the Auto Suture™ ENDO GIA™ Stapler. A clinical literature search was also performed to demonstrate and support the clinical application of the device for the resection and transection of liver.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2006

United States Surgical
% Mr. Frank Gianelli
Senior Associate, Regulatory Affairs
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K061095
Trade/Device Name: Auto Suture™ ENDO GIA™ Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW & GAG
Dated: April 17, 2006
Received: April 19, 2006

Dear Mr. Gianelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Mr. Frank Gianelli

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K061095

Device Name: Auto Suture™ ENDO GIA™ Stapler

Indications For Use:

The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K061095



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2006

United States Surgical
% Mr. Frank Gianelli
Senior Associate, Regulatory Affairs
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K061095

Trade/Device Name: Auto Suture™ ENDO GIA™ Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW & GAG
Dated: April 17, 2006
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Page 2 – Mr. Frank Gianelli

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Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkersen". The signature is written in a cursive style with a large initial "M".

Mark N. Melkersen
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K061095

Device Name: Auto Suture™ ENDO GIA™ Stapler

Indications For Use:

The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

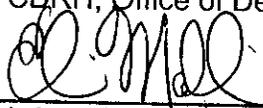
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K061095

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 20, 2006

UNITED STATES SURGICAL, A DIVISION 510(k) Number: K061095
150 GLOVER AVE. Received: 19-APR-2006
NORWALK, CT 06856 Product: AUTO SUTUR ENDO GIA
ATTN: FRANK GIANELLI STAPLERS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health



Healthcare

United States Surgical

2061095
United States Surgical
150 Glover Avenue
Norwalk, CT 06856

Main: 203-845-1000
www.tycohealthcare.com

April 17, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

K-19-

Re: **"510(k) Notification" (21 CFR 807.90(e))**
• **Traditional 510(k) for Auto Suture™ ENDO GIA™ Staplers**

Dear Madam/Sir:

United States Surgical is submitting this Traditional 510(k) in duplicate to report a modification for our currently marketed Auto Suture™ ENDO GIA™ Staplers. The modification is the inclusion of a specific indication as a subset of the general indication for the Auto Suture™ ENDO GIA™ Staplers. The specific indication concerns the use of the ENDO GIA™ Stapler on liver tissue as stated below.

Indications for Use

The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. **It be used for transection and resection of liver substance, hepatic vasculature and biliary structures.**

Based on the rationale presented in the November 4, 1998 document "Guidance for Industry on General/Specific Intended Use", we are submitting this Traditional 510(k) for clearance of this specific indication.

Administrative Information:

- a. Company Name: United States Surgical
a division of Tyco Healthcare Group LP
- b. Company Address: 150 Glover Ave.
Norwalk, CT 06856
- c. Establishment Registration No: 1219161
- d. Contact Person: Frank Gianelli
Senior Associate, Regulatory Affairs
United States Surgical
150 Glover Avenue
Norwalk, CT 06856
- e. Trade/Proprietary Name: Auto Suture™ ENDO GIA™ Staplers
- f. Common/Usual Name: Surgical Stapler with Implantable Staple

- g. Classification Name: Staple, Implantable
- h. Classification Panel Name: General and Plastic Surgery
- i. FDA Panel Number: 79
- j. Product Code: GDW
- k. Device Class: Pursuant to 21 CFR 878.4750, an implantable staple is a Class II device.
- l. Predicate Device(s): Auto Suture™ ENDO GIA™ Surgical Staplers
- m. Performance Standards: Pursuant to Section 514 of the Act and 21 CFR Part 880, no performance standards have been established for this device.

Design and Use of the Device:

The following principal factors about the design and use of the Auto Suture™ Endo GIA™ Staplers are shown in the table below.

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?	√	
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?	√	
Is the device implanted?	√	

Terms used in this submission, including the use of the term "substantially equivalent" are used in the particular context of requesting a determination that the product described in this submission may be marketed in accordance with section 510(k) of the Food, Drug and Cosmetic Act. The terms and descriptions set forth in this submission are not intended to and should not have any effect on the determination of any patent infringement issue or litigation. As required by 21 CFR §807.87, this Premarket Notification, to the best of our knowledge, and all information contained here within, is truthful and accurate and no material fact has been omitted.



Healthcare

United States
Surgical

United States Surgical
150 Glover Avenue
Norwalk, CT 06856

Main: 203-845-1000
www.tycohealthcare.com

We consider our intent to market this device as confidential commercial information and request that it be treated as such by the FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

United States Surgical believes that sufficient information and data are contained in this submission to enable FDA to reach a determination of substantial equivalence within a reasonable time period. In the event that additional information is required, please contact the undersigned.

Sincerely,

Frank Gianelli
Senior Associate, Regulatory Affairs

Telephone: (203) 492-5352
Fax: (203) 492-5029
Email: frank.gianelli@tycohealthcare.com

w/attachment

**510(k) Premarket Notification
for
Auto Suture™ ENDO GIA™ Staplers**

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Appendix 3	Full Articles of Relevant Clinical Literature - Studies	A3-1

Note: CDRH Guidance for Industry and FDA Staff, “Format for Traditional and Abbreviated 510(k)s”, dated August 12, 2005, has been used in compiling this submission.

**Screening Checklist
For All Premarket Notification [510(k)] Submissions**

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

- Special 510(k) – Do Sections 1 and 2
- Abbreviated 510(k) – Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided – Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present [Page(s)]	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510]] Manual.	16-18	
Table of Contents.	2	
Truthful and Accurate Statement.	23	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	16-17	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	17	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510]] Manual.	29, A1-1 to A1-6	
Statement of Indications for Use that is on a separate page in the premarket submission.	20	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510]] Manual.	26-28	
510(k) Summary or 510(k) Statement.	22	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	25	
Identification of legally marketed predicate device.*	26	
Compliance with performance standards.* [See Section 514 of the Act and 21 CFR 807.87 (d).]	NA	NA
Class III Certification and Summary.**	NA	NA
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	NA
510(k) Kit Certification***	NA	NA

* May not be applicable for Special 510(k)s.

** Required for Class III devices, only.

*** See pages 3-12 and 3-13 in the Premarket Notification [510]] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present [Page(s)]	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	NA	NA
A description of the modified device and a comparison to the sponsor's predicate device.	NA	NA
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	NA	NA
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):	NA	NA
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	NA	NA
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	NA	NA
c. A Declaration of Conformity with design controls that includes the following statements:	NA	NA
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	NA	NA
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	NA	NA

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present [Page(s)]	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)	NA	NA
For a submission, which relies on a recognized standard, a declaration of conformity	NA	NA
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.	NA	NA
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.	NA	NA
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.	NA	NA
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.	NA	NA

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present [Page(s)]	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	30	
b) Sterilization and expiration dating information:	29	
i) sterilization process	29	
ii) validation method of sterilization process	29	
iii) SAL	29	
iv) packaging	29	
v) specify pyrogen free	29	
vi) ETO residues	29	
vii) radiation dose	NA	NA
viii) Traditional Method or Non-Traditional Method	29	NA
c) Software Documentation:	NA	NA

1. Medical Device User Fee Cover Sheet (Form FDA 3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: Write the Payment Identification number on your check.	
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a . You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) TYCO HEALTHCARE LLP 150 GLOVER AVENUE NORWALK CT 06856 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)		2. CONTACT NAME Frank Gianelli 2.1 E-MAIL ADDRESS frank.gianelli@tycohealthcare.com 2.2 TELEPHONE NUMBER (include Area code) 203-492 5352 2.3 FACSIMILE (FAX) NUMBER (Include Area code) NO DATA	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)			
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)			
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)			

(b)(4) Trade Secret Process
Product Specs

(b)(4) Trade Secret Process

(b)(4) Trade Secret Process

22-Feb-2006

Form FDA 8601 (08/2003)
Close Window

Print Cover sheet

2. CDRH Premarket Review Submission Cover Sheet

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission: 4/17/2006
 User Fee Payment ID Number: (b)(4) Trade Secret Process - Product Specs
 FDA Submission Document Number (if known):

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name United States Surgical, a Division of Tyco Healthcare Group, LP		Establishment Registration Number (if known) 1219161	
Division Name (if applicable)		Phone Number (including area code) (203) 492-5352	
Street Address 150 Glover Avenue		FAX Number (including area code) (203) 492-5029	
City Norwalk	State / Province CT	ZIP/Postal Code 06850	Country USA
Contact Name Frank Gianelli			
Contact Title Senior Associate, Regulatory Affairs		Contact E-mail Address frank.gianelli@tycohealthcare.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input checked="" type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	GDW	2		3		4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K900129	1	Auto Suture™ Endo GIA™ Surgical Staplers	1	United States Surgical, a Division of Tyco Healthcare Group, LP
2	K892233	2	Auto Suture™ Endoscopic GIA™ Surgical Staplers	2	United States Surgical, a Division of Tyco Healthcare Group, LP
3	K801590	3	Auto Suture™ Disposable GIA™ Surgical Staplers	3	United States Surgical, a Division of Tyco Healthcare Group, LP
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Surgical Stapler with Implantable Staple

	Trade or Proprietary or Model Name for This Device		Model Number
1	Auto Suture™ ENDO GIA™ Staplers	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
K900129	K892233	K801590			
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code GDW	C.F.R. Section (if applicable) 878.4750	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)
 The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 1219161		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name United States Surgical, a Division of Tyco Healthcare Group, LP			Establishment Registration Number 1219161		
Division Name (if applicable)			Phone Number (including area code) (203) 492-5352		
Street Address 150 Glover Avenue			FAX Number (including area code) (203) 492-5029		
City Norwalk		State / Province CT	ZIP/Postal Code 06850	Country USA	
Contact Name Frank Gianelli		Contact Title Senior Associate, Regulatory Affairs		Contact E-mail Address frank.gianelli@tycohealthcare.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

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SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

3. 510(k) Cover Letter



Healthcare

United States Surgical

United States Surgical
150 Glover Avenue
Norwalk, CT 06856

Main: 203-845-1000
www.tycohealthcare.com

April 17, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: **"510(k) Notification" (21 CFR 807.90(e))**
• **Traditional 510(k) for Auto Suture™ ENDO GIA™ Staplers**

Dear Madam/Sir:

United States Surgical is submitting this Traditional 510(k) in duplicate to report a modification for our currently marketed Auto Suture™ ENDO GIA™ Staplers. The modification is the inclusion of a specific indication as a subset of the general indication for the Auto Suture™ ENDO GIA™ Staplers. The specific indication concerns the use of the ENDO GIA™ Stapler on liver tissue as stated below.

Indications for Use

The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. **It be used for transection and resection of liver substance, hepatic vasculature and biliary structures.**

Based on the rationale presented in the November 4, 1998 document "Guidance for Industry on General/Specific Intended Use", we are submitting this Traditional 510(k) for clearance of this specific indication.

Administrative Information:

- a. Company Name: United States Surgical
a division of Tyco Healthcare Group LP
- b. Company Address: 150 Glover Ave.
Norwalk, CT 06856
- c. Establishment Registration No: 1219161
- d. Contact Person: Frank Gianelli
Senior Associate, Regulatory Affairs
United States Surgical
150 Glover Avenue
Norwalk, CT 06856
- e. Trade/Proprietary Name: Auto Suture™ ENDO GIA™ Staplers
- f. Common/Usual Name: Surgical Stapler with Implantable Staple

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Healthcare

United States Surgical

United States Surgical
150 Glover Avenue
Norwalk, CT 06856

Main: 203-845-1000
www.tycohealthcare.com

- g. Classification Name: Staple, Implantable
- h. Classification Panel Name: General and Plastic Surgery
- i. FDA Panel Number: 79
- j. Product Code: GDW
- k. Device Class: Pursuant to 21 CFR 878.4750, an implantable staple is a Class II device.
- l. Predicate Device(s): Auto Suture™ ENDO GIA™ Surgical Staplers
- m. Performance Standards: Pursuant to Section 514 of the Act and 21 CFR Part 880, no performance standards have been established for this device.

Design and Use of the Device:

The following principal factors about the design and use of the Auto Suture™ Endo GIA™ Staplers are shown in the table below.

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?	√	
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?	√	
Is the device implanted?	√	

Terms used in this submission, including the use of the term "substantially equivalent" are used in the particular context of requesting a determination that the product described in this submission may be marketed in accordance with section 510(k) of the Food, Drug and Cosmetic Act. The terms and descriptions set forth in this submission are not intended to and should not have any effect on the determination of any patent infringement issue or litigation. As required by 21 CFR §807.87, this Premarket Notification, to the best of our knowledge, and all information contained here within, is truthful and accurate and no material fact has been omitted.



Healthcare

**United States
Surgical**

United States Surgical
150 Glover Avenue
Norwalk, CT 06856

Main: 203-845-1000
www.tycohealthcare.com

We consider our intent to market this device as confidential commercial information and request that it be treated as such by the FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

United States Surgical believes that sufficient information and data are contained in this submission to enable FDA to reach a determination of substantial equivalence within a reasonable time period. In the event that additional information is required, please contact the undersigned.

Sincerely,

Frank Gianelli
Senior Associate, Regulatory Affairs

Telephone: (203) 492-5352
Fax: (203) 492-5029
Email: frank.gianelli@tycohealthcare.com

w/attachment

4. Indications for Use Statement

Indications For Use

510(k) Number (if known): K061095

Device Name: Auto Suture™ ENDO GIA™ Stapler

Indications For Use:

The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(k) Summary

510(k) Summary of Safety and Effectiveness

SUBMITTER: United States Surgical, a division of Tyco Healthcare Group LP
150 Glover Avenue
Norwalk, CT 06856
Tel. No.: (203) 845-1000

CONTACT PERSON: Frank Gianelli
Senior Associate, Regulatory Affairs

DATE PREPARED: April 17, 2006

TRADE/PROPRIETARY NAME: Auto Suture™ ENDO GIA™ Stapler

COMMON/USUAL NAME: Staple, Implantable

CLASSIFICATION NAME: Staple, Implantable

PREDICATE DEVICE(S): Auto Suture™ ENDO GIA™ Stapler

DEVICE DESCRIPTION: The Auto Suture™ ENDO GIA™ Stapler places two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows. The size of the staples is determined by the selection of the 2.0 mm, 2.5 mm, 3.5 mm or 4.8 mm single-use loading unit (SULU). The ENDO GIA™ Stapler will accommodate any of the single-use loading units that are available in 30 mm, 45 mm and 60 mm sizes.

INTENDED USE: The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

TECHNOLOGICAL CHARACTERISTICS: The Auto Suture™ ENDO GIA™ Stapler is identical to the predicate device. The only change is the inclusion of a specific indication concerning the device's use on liver tissue as a subset of the general indication for the Auto Suture™ ENDO GIA™ Stapler.

MATERIALS: All components of the Auto Suture™ ENDO GIA™ Stapler are comprised of materials which are in accordance with ISO Standard 10993-1.

PERFORMANCE DATA: In-vivo animal tests were performed to support the inclusion of a specific indication as a subset of the general indication for the Auto Suture™ ENDO GIA™ Stapler. A clinical literature search was also performed to demonstrate and support the clinical application of the device for the resection and transection of liver.

6. Truthful and Accurate Statement

Premarket Notification

Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(j), I, Frank Gianelli, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Senior Associate, Regulatory Affairs of United States Surgical, a division of Tyco Healthcare Group LP, and in reliance thereupon, the data and information submitted in this Premarket Notification are truthful and accurate and that no material fact for a review of the substantial equivalence of this device has been knowingly omitted from this submission.



Frank Gianelli
Senior Associate, Regulatory Affairs
United States Surgical
a division of Tyco Healthcare Group LP

4/17/2006

Date

7. Class III Summary and Certification

This section does not apply.

8. Financial Certification or Disclosure Statement

This section does not apply.

9. Declarations of Conformity and Summary Reports

This section does not apply.

10. Executive Summary

United States Surgical received permission from FDA in 1980 to market the Auto Suture™ GIA™ Stapler (K801590) for use in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomoses. An endoscopic version of the GIA™ (K892233) was introduced in 1989 and a single use disposable version of the ENDO GIA™ (K900129) was introduced in 1990. As such, these surgical staplers have a long history of safe and efficacious use and have become a standard part of the surgeon's armamentarium.

The currently marketed Auto Suture™ ENDO GIA™ Stapler is an articulating, disposable, linear stapler that simultaneously transects and staples various types of internal tissues. It fires two sets of three staggered rows of titanium staples and simultaneously divides the tissue between the two sets of rows. It can be used in both endoscopic and open surgical procedures. It is available in multiple sizes and for endoscopic procedures it can be introduced and used through appropriately sized trocar endoscopic access cannulae.

Historically, linear surgical staplers such as the Auto Suture™ ENDO GIA™ Staplers have been used during liver resection to transect the hepatic and portal branches in order to control blood loss during the procedure. However, hepato-biliary surgeons in the USA and Europe have introduced liver resection techniques during which linear surgical staplers, specifically the Auto Suture™ ENDO GIA™ Stapler, are used not only for transection of the hepatic vasculature but also for the transection of hepatic parenchyma.

Therefore, United States Surgical now submits this traditional 510(k) to expand the indications statement for its currently marketed Auto Suture™ GIA™ Staplers. The proposed modification is the inclusion of a specific indication as a subset of the general indication. The specific indication concerns the use of the ENDO GIA™ for transection and resection of liver tissue as follows:

Indications for Use: (changes noted in bold type)

The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. **It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.**

To support the addition of the specific indication regarding liver tissue, United States Surgical performed the following:

(b)(4) Trade Secret Process - Product Specs

- A search and review of existing clinical literature to demonstrate the clinical application and outcomes of the subject devices in stapling across liver. Refer to Section 20 of this submission.

This submission is based on the rationale presented in the November 4, 1998 document "Guidance for Industry on General/Specific Intended Use." Factors considered for substantial equivalence include demonstrated understanding by the medical community that this specific use is a subset of the general use and that it does not introduce new risks, significantly impact public health, or change the design, performance, or clinical endpoints of the device.

11. Device Description

11.1 Product Description

Note: To facilitate this product description, a product brochure is included in Appendix 2 of this submission.

The Auto Suture™ ENDO GIA™ Stapler is an articulating, disposable, linear stapler that simultaneously transects and staples various types of internal tissues. It fires two sets of three staggered rows of titanium staples and simultaneously divides the tissue between the two sets of rows. Each set of rows will begin and end with two staples. It can be used in both endoscopic and open surgical procedures. It is available in multiple sizes and for endoscopic procedures it can be introduced and used through appropriately sized trocar endoscopic access cannulae.

The device consists of an instrument, an elongated shaft, a single use loading cartridge containing the staples and the cutting blade, and an anvil on which to form the staples. The cartridge and anvil portion may be articulated through various angles to provide increased access and versatility. It also locks into a rigid coaxial orientation with the shaft to allow passage through a trocar with relative ease. There are 3 rigid positions of articulation including the 0° (entry position), 22° and 45° (maximum articulation).

The Instrument has a trigger that is manually squeezed once to close the anvil to clamp the tissue. Once the anvil is fully closed, it securely retains the tissue until it is opened. To fire the instrument, a safety must be physically and intentionally disengaged after full clamp-up. Once the safety has been disengaged, the trigger can be squeezed additional times to fire the staples and advance the cutting blade. The number of firing squeezes will increase with cartridge length. The cartridge assembly has graphics to indicate distance fired and cut line.

At any time after clamp up, the anvil may be opened by fully retracting the manual retraction knobs. If the instrument's safety has been disengaged, and a firing stroke initiated, the process of retraction will engage a lock-out preventing the cartridge from being re-fired to prevent injury. Proper loading of the SULU is required to allow firing. Improper loading will prevent firing. The SULU will not be able to be disengaged and removed unless the device is in the unclamped state. Likewise, the instrument's retraction knobs must be in the load/unload position to load a new SULU.

11.2 Sterilization, Manufacture, Materials, and Engineering Specifications

The Auto Suture™ ENDO GIA™ Staplers are the currently marketed predicate staplers, and, therefore, the materials and components, manufacturing facility, and engineering specifications cleared by the previous premarket notifications remain the same. The subject devices are manufactured from materials that have passed biocompatibility testing for their intended patient contact profile according to ISO 10993-1, and are sterilized via a validated ethylene oxide (ETO) cycle. There have been no modifications to the devices. This premarket notification is being submitted only to expand the indications for use to include a specific indication as a subset of the general indication. The specific indication concerns the use of the ENDO GIA™ Staplers for transection and resection of liver tissue.

12. Substantial Equivalence Discussion

12.1 Identification of Predicate Device

Trade/Proprietary Name: Auto Suture™ ENDO GIA™ Staplers
Common/usual name: Surgical Stapler with Implantable Staple
Classification name: Staple, Implantable
Class/Panel: Class II, 79-GDW, 21 CFR 878.4750
510(k) Submitter/Holder: United States Surgical
a division of Tyco Healthcare Group LP
150 Glover Ave.
Norwalk, CT 06856
510(k) no.: K900129

The subject device in this premarket notification is the Auto Suture™ ENDO GIA™ Stapler, which is also the currently marketed predicate device identified above. Therefore, the devices are identical with regard to design, features, function, components, materials, sterilization, shelf life, packaging and manufacturing facility. There have been no modifications to the device. This premarket notification is being submitted only to expand the indications for use to include a specific indication as a subset of the general indication. The specific indication concerns the use of the ENDO GIA™ Staplers for transection and resection of liver tissue.

12.2 Substantial Equivalence Decision Making Process

The "510(k) 'Substantial Equivalence' Decision-Making Process (Detailed)" decision tree (ODE Guidance Memo # K86-3) was used to demonstrate the substantial equivalence of the Auto Suture™ ENDO GIA™ Staplers to their predicate devices.

- 1. Does the new device have the same indication statements?**
No, the general indications for use are the same, but a specific indication is being added as a subset of the general indications.
- 2. Do the differences alter the intended therapeutic/diagnostic effect?**
No, the specific indication, which is a subset of the general indication, does not alter the intended therapeutic/diagnostic effect.
- 3. Does the new device have the same technological characteristics, e.g., design, materials, etc.?**
Yes, the new device is the same as the currently marketed device.
- 4. Are the descriptive characteristics precise enough to ensure equivalence?**
Yes, the results of animal performance tests and the descriptive characteristics from the attached clinical literature are precise enough to ensure equivalence.

Decision-Making Criteria from the November 4, 1998 document "Guidance for Industry on General/Specific Intended Use" for determining substantial equivalence:

1. Does a specific use introduce new risks not normally associated with the general use of the device?

No, the contraindications, cautions and warnings associated with the ENDO GIA™ Stapler remain the same. The ENDO GIA™ Stapler may be used for transection and ligation of liver tissue, vasculature, and biliary structures in the same manner described in its general use as long as the user also adheres to the contraindications, warnings and precautions in the Instructions For Use.

2. Does a specific use impact public health to a significantly greater degree than the general use of the device?

No, the specific use is a subset of the general use and does not significantly affect public health to a greater degree than the general use of the device as long as the specific use is followed.

3. Is there a body of evidence available to the agency regarding a proposed specific use that reflects existing understanding by the medical community that the more specific use is a subset of the general use, rather than a new intended use?

Yes, there is relevant clinical literature on the specific use of these staplers for the transection and resection of liver tissue. This clinical literature shows that the medical community understands that these staplers when used for the transection and resection of liver tissue are being used in the same manner as when used for the general use. The relevant clinical literature is summarized in section 20 and fully presented in Appendix 3 to substantiate the safety and efficacy of this specific use as a subset of the general use, rather than as a new intended use. In addition, the safety and effectiveness of the stapler are related to tissue cutting, staple placement, staple formation, biocompatibility and sterility for both the specific indication and the general indication.

4. To what degree can the performance or clinical endpoints used to evaluate the general use be applied to the specific use?

For its general use, the clinical endpoint of the stapler is to transect or resect tissue via the placement of multiple staggered rows of staples and to divide the stapled tissue while achieving hemostasis. When used for the specific use in the transection or resection of the liver, the clinical endpoint is the same.

5. To what degree is the device used by the physician intended to perform a task as opposed to "being" the treatment?

The device is intended to be used in the same manner when used for liver transection and resection as when used for resection, transection and creation of anastomoses in both open and endoscopic procedures. For both the specific use and the general use, the device is intended to perform a task and is not intended as being the treatment.

6. To what degree does another product not routinely needed for the general use need to be used in conjunction with the device to achieve the specific use safely and effectively?

It is not necessary to use another product to achieve the specific use safely and effectively.

7. To what extent does a modification to a medical device to facilitate the specific use render it less applicable to other aspects of the general use?

There have been no modifications made to the device.

12.3 Substantially Equivalence Determination

The Auto Suture™ ENDO GIA™ Staplers are the currently marketed predicate staplers, and, therefore, the materials and components, manufacturing facility, and engineering specifications cleared by the previous premarket notification remain the same.

Substantial Equivalence Chart

	Auto Suture™ ENDO GIA™ Staplers (Subject)	Auto Suture™ ENDO GIA™ Staplers (Predicate)
Design	The Auto Suture™ ENDO GIA™ Staplers are designed to place two triple, staggered rows of titanium staples and simultaneously the knife divides the tissue in between. The instrument is designed for multiple use during a single surgical procedure. It can be reloaded up to 25 times for a total of 25 applications. The disposable loading unit can articulate at 22° and 45° in both directions by moving the proximal knob on the stapler.	Same
Biocompatibility	The subject device is manufactured from materials that have passed biocompatibility testing for their intended patient contact profile according to ISO 10993-1.	Same
Packaging	The Auto Suture™ ENDO GIA™ Staplers are packaged in a sterile tray with a TYVEK lid. Each individual tray is packaged in a display box. Both the sterile tray and the display box package have appropriate labeling.	Same
Stability/Shelf Life	The subject device has been validated and labeled as such to indicate a 5 year expiration date.	Same
Sterilization	The subject device is sterilized via a validated ethylene oxide (ETO) cycle.	Same
Indications	The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.	The Auto Suture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses.
Contraindications, Warnings and Precautions	Same	Same

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13. Proposed Labeling

A draft Instruction for Use for a representative Auto Suture™ ENDO GIA™ Stapler is included in Appendix 1 of this submission.

14. Sterilization and Shelf Life

14.1 Sterilization

This premarket notification does not alter the sterilization method of the Auto Suture™ ENDO GIA™ Stapler.

Pursuant to the "Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA", dated August 30, 2002 the following information is provided:

Sterilization method used: The Auto Suture™ ENDO GIA™ Stapler is sterilized via a validated Ethylene Oxide (EO) cycle, which is a traditional method of sterilization [Ethylene Oxide (EO) with devices placed in a fixed chamber].

Description of method used to validate the sterilization cycle: The validation conforms with AAMI/ANSI/ISO 11135:1994, "Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization."

Description of the packaging used to maintain product sterility: The Auto Suture™ ENDO GIA™ Stapler is packaged in a PVC blister to which is sealed a coated TYVEK cover.

Ethylene Oxide (EO) Residuals: The evaluation of EO residuals was conducted in accordance with AAMI/ANSI/ISO 10993-7:1995, "Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals" and the Auto Suture™ ENDO GIA™ Stapler complies with allowable limits on EO residual levels as stated in AAMI/ANSI/ISO 10993-7:1995.

Pyrogenicity Evaluation: Not applicable, since this device is not labeled "pyrogen free".

Sterility Assurance Level: The sterilization cycle for the Auto Suture™ ENDO GIA™ Stapler will result in a minimum Sterility Assurance Level (SAL) of 1×10^{-6} .

Radiation Dose: Not applicable, since radiation sterilization is not used for this device.

14.2 Shelf Life/Stability

This premarket notification does not alter the shelf life and stability of the Auto Suture™ ENDO GIA™ Stapler.

The shelf life of the ENDO GIA™ Stapler is evaluated in accordance with U.S. Surgical Standard Operating Procedures. All samples are sterilized by Ethylene Oxide sterilization prior to the initiation of the stability evaluation, and stored at controlled room temperature conditions as well as elevated temperatures for accelerated aging. The functional and visual evaluations of the product meet the product label claim specifications.

15. Biocompatibility

This premarket notification does not alter the materials used in the ENDO GIA™ Staplers or the manufacturing methods for processing these materials.

The Auto Suture™ ENDO GIA™ Staplers are comprised of materials, which have passed biocompatibility testing in accordance with ISO Standard 10993-1 for their intended patient contact profile. These tests have demonstrated that the ENDO GIA™ Staplers comply with the requirements of ISO 10993-1.

16. Software

This section does not apply.

17. Electromagnetic Compatibility and Electrical Safety

This section does not apply.

18. Performance Testing – Bench

This section does not apply.

19. Performance Testing – Animal

The following tests were performed to support the specific indication as a subset of the general indication that the ENDO GIA™ Surgical Stapler may be used for transection and resection of liver substance, hepatic vasculature and biliary structures, provided adequate precautions are taken to verify hemostasis.

Test:

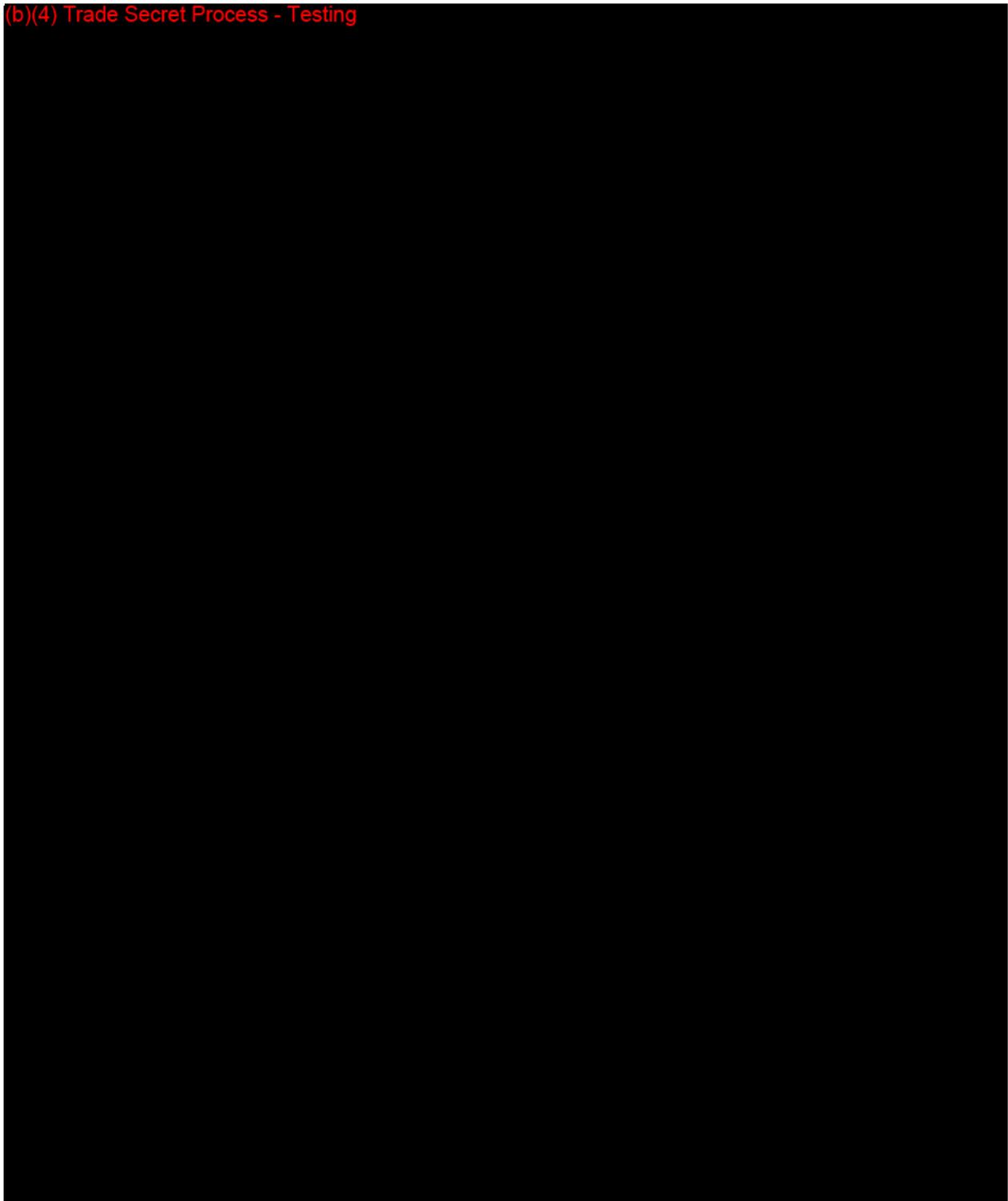
Evaluation of Liver Resection in Canine

Description of Test Protocol:

(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



20. Performance Evaluation - Clinical

The submission of this Traditional 510(k) is based, in part, on an understanding by the medical community that stapling devices can be used for transection and resection of liver substance, hepatic vasculature and biliary structures, provided adequate precautions are taken to verify hemostasis. Therefore, the Auto Suture™ ENDO GIA™ Staplers can be considered to be safe and effective for this clinical application when used within the context of this specific indication, which is a subset of the general indications.

United States Surgical performed a literature search to compile the relevant clinical literature to demonstrate the clinical application of stapling devices for the transection and resection of liver. The following clinical literature searches were performed.

Website Searched; Search Terms; Search Criteria	Search Results	Relevant Articles [used in 510(k)]	Not relevant & why (review of abstracts or ordered articles)
PubMed Search: "Liver resection using surgical instruments" (English, Abstract)	2 articles	0	2 • Staplers were not used.
PubMed Search: "Liver resection with Endo GIA" (English, Abstract)	2 articles	0	2 • Stapler used for different part of procedure.
PubMed Search: Stapler Hepatectomy (English, Abstract)	12 articles	1 <u>see Bibliography*:</u> reference 5	11 • 2 from previous search. • 1 focused on stapler reinforcement. • 2 wrong procedure. • 1 was an animal study. • 4 did not contain enough information. • 1 was not a clinical study.
PubMed Search: "Danielle Cherqui" (English, Abstract)	20 articles	0	20 • stapler used for different part of procedure and repeat resections.
PubMed Search: "Liver resection" staple (English, Abstract)	10 articles	1 <u>see Bibliography:</u> reference 6	9 • 2 were from a previous search. • 2 in foreign language. • 1 does not use staplers. • 2 used stapler for different part of procedure. • 1 was an animal study. • 1 was not a clinical study.
PubMed Search: "An initial experience and evolution of laparoscopic hepatic resectional surgery" and Buell (English)	1 article	1 <u>see Bibliography:</u> reference 1	

Website Searched; Search Terms; Search Criteria	Search Results	Relevant Articles [used in 510(k)]	Not relevant & why (review of abstracts or ordered articles)
NLM Gateway Search: hepatectomy and stapling and Endo GIA (English)	1 article	1 <u>see Bibliography:</u> reference 3	
PubMed Search: "laparoscopic liver resection" and Buell (English)	1 article	1 <u>see Bibliography:</u> reference 2	
NLM Gateway Search: hepatectomy and liver and stapling and endoscopic (English)	5 articles	1 <u>see Bibliography:</u> reference 4	4 <ul style="list-style-type: none"> • 2 health topics for consumers. • 2 articles we already have.
Articles ordered that were referenced in one or more of the above applicable articles.	4 articles	0	4 <ul style="list-style-type: none"> • 1 used stapler for different part of procedure. • 1 article we never received. • 2 were not clinical studies.
Articles ordered based on input from Marketing or articles received from other USS Dept's (Marketing, R&D, QA, etc.).	1 article	0	1 <ul style="list-style-type: none"> • was not a clinical study.

* The Bibliography is located in Appendix 3 of this submission.

The relevant articles included in this submission fall into the following category.

- 6 articles summarized in Table 1 of this Section represent prospective and retrospective studies of liver hepatic surgery encompassing 790 patients in which endovascular staplers were used. The full articles along with a bibliography are included in Appendix 3 of this submission.

These clinical literature samples accurately represent the established understanding of the medical community and demonstrate the use of the Auto Suture™ ENDO GIA™ Staplers for liver tissue transection and resection.

Table 1

The below table is a summary of the relevant clinical literature included in this submission representing prospective and retrospective studies of liver hepatic surgery encompassing 790 patients in which endovascular staplers were used. The full articles are included in Appendix 3 of this submission

Article	Type of Study/Discussion	# of Patients	How were Endo Staplers used	Results/conclusion with respect to using Endo Staplers
<p>Buell JF, Thomas MJ, Doty TC, Gersin KS, Merchen TD, Gupta M, Rudich SM, Woodle ES. "An Initial Experience and evolution of Laparoscopic Hepatic Resectional Surgery" (Surgery. 2004 Oct; 136(4): 804-11)</p>	<p>Background – The use of minimally invasive procedures has revolutionized modern surgery. Only recently has laparoscopy been introduced for use in hepatic surgery.</p> <p>Methods - Patient demographics, tumor characteristics, and outcomes were evaluated for all initial cases of laparoscopic hepatic resection.</p> <p>Results - Twenty-one resections were performed in 17 patients; 5 were performed for malignancy, of which 3 had underlying cirrhosis, and the remaining 12 for benign symptomatic disease. Mean patient age was 55.4 (range, 24-82 years). The mean number of lesions was 1.4 (range, 1-5), having an average size of 7.6 cm (range, 2-30 cm). Mean operative time was 2.8 hours (range, 2-5 hours) hours. Most resections involved 1 or more Couinaud segments. Mean blood loss was 288 cc (range, 50-150 cc). Complications included re-operation for hemorrhage (n=2), biliary leakage (n=1), and death from hepatic failure (n=1). Mean length of stay was 2.9 days (range, 1-14). When compared with our series of 100 patients who underwent open hepatic resection for benign tumors, significantly greater means (P <.05) were noted for blood loss (485 cc), operative time (4.5 hours), and length of stay (6.5 days).</p>	<p>17 patients</p>	<p>"In 2002, the authors initiated a hepatic resection program at the University of Cincinnati Hospital.... Candidacy for hepatic resection was determined solely by the anatomic positioning of tumors in association with the vena cava and major hepatic vascular structures (hepatic vein confluence and portal bifurcation)... Thus, the indication for laparoscopic hepatic resection of patients with hepatocellular cancer (HCC) included the presence of peripheral tumors and any Child's classification..... The liver is intraoperatively evaluated with the aid of a laparoscopic ultrasound probe. ... Slow dissection was performed to decrease the overall width of the parenchyma to be resected. After outlining the extent of the resection to be performed, the hepatic parenchyma was transected with the use of endovascular-articulating staplers (Tyco). When an area that could not easily be traversed with a single stapler load was identified, use of the harmonic scalpel to further dissect the hepatic substance made subsequent stapler use more effective."</p>	<p>Conclusions - Laparoscopic hepatic surgery, though complex, can be performed safely and efficaciously. Minimally invasive surgery appears to provide several distinct advantages over traditional open hepatic surgery. However, techniques for the laparoscopic control of bleeding and bile leak remain in their infancy.</p> <p>"In the author's initial experience, the application of multiple staple loads, facilitated by a hand-assist device, has not only made this procedure safe but has significantly shortened hospital stays compared to those of a historical control."</p>

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Auto Suture™ ENDO GIA™ Surgical Stapler

Article	Type of Study/Discussion	# of Patients	How were Endo Staplers used	Results/conclusion with respect to using Endo Staplers
<p>Buell JF, Koffron AJ, Thomas MJ, Rudich S, Abecassis M, Woodle S. "Laparoscopic Liver Resection" (J Am Coll Surg. 2005 Mar;200(3):472-80)</p>	<p>Background – Laparoscopic surgery has evolved over the last two decades. Solid organ surgery is the next forefront for laparoscopic surgery. Hepatic surgery is the most challenging and controversial.</p> <p>Study design - Retrospective review of surgical techniques employed during the first 100 hepatic resections performed by two surgeons at their respective institutions.</p> <p>Results – This study reviews the evolution of surgeon positioning, port placements and advances in surgical technique. A brief review of patient outcomes identifies a variable distribution of segmental and lobar resections performed in both cirrhotic and non-cirrhotic patients. Significant (8 cm; range 1 to 25 cm) size solid and cystic tumors were approached with short mean operative time (2.2 hours) and a complication rate of 23%.</p>	<p>100 patients</p>	<p>"The parenchymal transection is incised and reduced with the ultrasound dissector or tissueink (argon beam) device. Major hepatic resection is then accomplished with the application of endovascular staplers. Placement of the staplers are guided by the intracorporeal hand. Staplers are liberally utilized to divide vessels, bile ducts and parenchyma. After transection, the liver edge is argon beam coagulated and sheets of pro-coagulation sheets are applied."</p>	<p>"Conclusions - With careful and thoughtful planning laparoscopic hepatic resection can be performed safely in a wide variety of lesions. This must be premised on appropriate training in both hepatobiliary and laparoscopic surgery."</p>

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Article	Type of Study/Discussion	# of Patients	How were Endo Staplers used	Results/conclusion with respect to using Endo Staplers
<p>Schemmer P, Friess H, Hinz U, Mehrabi A, Kraus TW, Zgraggen K, Schmid J, Uhl W, Buchler MW. "Stapler Hepatectomy is a Safe Dissection Technique: Analysis of 300 Patients" (World J Surg. 2006 Mar;30(3):419-30)</p>	<p>Background - In many surgical procedures, stapling devices have been introduced for safety and to reduce the overall operative time. Their use for transection of hepatic parenchyma is not well established. Thus, the feasibility of stapler hepatectomy and a risk analysis of surgical morbidity based on intraoperative data have been prospectively assessed on a routine clinical basis.</p> <p>Materials and Methods - From October 1, 2001, to January 31, 2005, a total of 416 patients underwent liver resection in our department.</p> <p>During this period Endo GIA vascular staplers were used for parenchymal transection in 300 cases of primary (22%) and metastatic (57%) liver cancer, benign diseases (adenoma, focal nodular hyperplasia [FNH], cysts) (14%), gallbladder carcinoma (2%), and other tumors (5%). There were 193 (64%) major resections (i.e., removal of three segments or more) and 107 minor hepatic resections. Additional extrahepatic resections were performed in 44 (15%) patients.</p> <p>Results - Median values for operative time and intraoperative hemorrhage were 210 minutes and 700 ml, respectively. Further, transfusion of RBC and FFP was needed in 17% and 11% of patients, respectively. A postoperative ICU stay for >2 days was required in 18% of patients. The median postoperative hospital stay was 10 days (IQR 8-14 days). The most frequent surgical complications were bile leak (8%), wound infection (3%), and pneumothorax (2%). In 7% of cases after stapler hepatectomy a relaparotomy was necessary. Treated medical complications were pleural effusion (7%), renal insufficiency (5%), and cardiac insufficiency (3%). Risk assessment revealed that both operative time and indication for resection had significant impact on surgical morbidity. Mortality (4%) and morbidity (33%) were comparable to other high-volume centers performing conventional liver resection techniques.</p>	<p>300 patients</p>	<p>The appropriate hepatic veins are divided with the endo vascular stapler. After the transectional line was marked, the liver capsule was divided with diathermy. For subsequent dissection of the hepatic parenchyma, liver tissue was fractured stepwise with a vascular clamp and subsequently divided with endo vascular stapling. If necessary, intraoperative ultrasound is used to guide the dissection.</p>	<p>Conclusion - In conclusion, stapler hepatectomy can be used in a routine clinical setting with a low incidence of surgical complications.</p>

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Auto Suture™ ENDO GIA™ Surgical Stapler

Article	Type of Study/Discussion	# of Patients	How were Endo Staplers used	Results/conclusion with respect to using Endo Staplers
<p>Kaneko et al. "Hepatic resection using stapling devices" (The American Journal of Surgery 187 (2004) 280-284).</p>	<p>Background - The progress and development of stapling devices has been remarkable. They have become indispensable for gastrointestinal diseases and are increasingly utilized in laparoscopic operations. Liver surgery applications for this technique are continuing to emerge, and in this study, we introduced the use of stapling devices to hepatic surgery. METHODS: We examined the operative procedure and efficacy of hepatic resections using stapling devices as follows: transection of Glisson's pedicle and the hepatic vein using endolineal stapling devices in right and left lobectomies; bisegmentectomy II and III en masse using a stapling device; and application of endolineal stapling devices to vessel transections and dissections of the hepatic parenchyma in laparoscopic hepatectomies.</p> <p>Results - It was considered useful to tactfully apply stapling devices to vessel transections and dissections of the hepatic parenchyma in order to simplify the operative procedures of right or left lobectomies and lateral segmentectomies. Furthermore, the use of endoscopic stapling devices was an acceptable alternative to vessel transections and dissections of the hepatic parenchyma in laparoscopic hepatectomies.</p>	<p>15 patients</p>	<p>The operative procedure and efficacy of hepatic resections using stapling devices are as follows: transection of Glisson's pedicle and the hepatic vein using endolineal stapling devices in right and left lobectomies; bisegmentectomy II and III en masse using a stapling device; and application of endolineal stapling devices to vessel transections and dissections of the hepatic parenchyma in laparoscopic hepatectomies.</p>	<p>"Endoscopic stapling devices are also very useful for transection of the intrahepatic vessels and liver parenchyma especially in cases with bisegmentectomy II and III or the pedunculated tumor, as long as it is possible to insert the hepatic parenchyma planned for resection. In the authors' experience, it is useful to employ stapling devices in dissecting the hepatic parenchyma and transecting vessels in order to simplify hepatic lobectomies and bisegmentectomy II and III. In addition, stapling devices could be applied to laparoscopic hepatectomies and could become one of the new and less evasive liver operations"</p> <p>"Conclusions - We believe that stapling devices will become utilized in liver surgery hereafter."</p>

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Auto Suture™ ENDO GIA™ Surgical Stapler

Article	Type of Study/Discussion	# of Patients	How were Endo Staplers used	Results/conclusion with respect to using Endo Staplers
<p>Nicholas O'Rourke and George Fielding "Laparoscopic Right Hepatectomy: Surgical Technique" (J Gastrointest Surg. 2004 Feb; 8(2):213-6).</p>	<p>Background - The objective of this study was to demonstrate the safety of laparoscopic right hepatectomy for benign or malignant disease. Many reports document the success of minor or segmental liver resections performed laparoscopically. Major hepatic resection has rarely been reported. This report documents our experience with 12 laparoscopic right hepatectomies.</p> <p>Methods - Ten patients had suspected malignancy, but all had lesions well clear of the midplane of the liver. The surgery followed three distinct phases: (1). Portal dissection during which diathermy and harmonic shears are used, clips are applied to the right hepatic duct and right hepatic artery, and a vascular stapler is used to divide the right portal vein; (2). dissection of the vena cava, which is usually done by tunneling below the liver using harmonic shears, clips, and a linear stapler to divide the right hepatic vein; and (3). parenchymal division during which harmonic shears and multiple firings of linear staplers are used to divide the liver substance.</p> <p>Results - In five patients the procedure was completed totally laparoscopically, five patients had a laparoscopic-assisted procedure, and two patients had to be converted to formal open hepatectomy. Four patients required blood transfusion. There were no deaths and two cases of major morbidity-bile leakage in one and wound dehiscence in one. The average hospital stay was 8 days, but for those whose operations were completed totally laparoscopically, 4 days was the average. Two of the nine patients with documented cancer have since died-one with widespread intrahepatic hepatocellular carcinoma and another with widespread metastatic melanoma after resection of a colorectal metastasis. Seven patients with colorectal cancer are alive and disease free with follow-up of 6 to 24 months.</p>	<p>12 patients</p>	<p>Parenchymal Division -Following the line of demarcation along the midline of the liver, harmonic shears and linear staplers are used to divide the liver. Up to nine vascular staplers have been used, insinuating the thin arm of the device through the liver substance, firing after resistance is reached. Bleeding can occur, most commonly from branches of the middle vein. This can be controlled by a repeat firing of the stapler, or suture ligation if the vessel is within the remaining liver."</p>	<p>Conclusions - Laparoscopic right hepatectomy is feasible in selected patients. It is technically demanding but can be safely accomplished by surgeons who have experience in advanced laparoscopic procedures and open hepatic surgery.</p>

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Auto Suture™ ENDO GIA™ Surgical Stapler

Article	Type of Study/Discussion	# of Patients	How were Endo Staplers used	Results/conclusion with respect to using Endo Staplers
<p>Smith DL, Ardens JF, Barnett CC Jr, Izzo F, Cury SA. "A prospective evaluation of ultrasound-directed transparenchymal vascular control with linear cutting staplers in major hepatic resections." Am J Surg. 2005 Jul;109(1):23-9.</p>	<p>A prospective evaluation of a ultrasound-directed technique of major hepatic resection using transparenchymal application of vascular staplers intending to minimize blood loss, operative time, and hepatic warm ischemia time.</p> <p>Methods - Beginning in 1998 many major hepatic resections for hepatic tumors were performed with ultrasound-directed transparenchymal application of vascular linear cutting staplers. An endoscopic flexible neck vascular linear cutting stapler was used for control of the hepatic veins.</p> <p>Results - From December 1998 to April 2003, 346 patients undergoing hepatic resection using this technique were identified from a prospective hepatobiliary tumor surgery database. Records were reviewed for blood loss, transfusion requirement, inflow occlusion (Pringle maneuver) time, overall operative time, and perioperative and postoperative complications. The average blood loss for all patients was 396 +/- 28.4 mL. The inflow occlusion time was 13.7 +/- .64 minutes with a total operative time of 140.7 +/- 3.7 minutes. Additional liver-related procedures were performed in 52% of the patients. The overall complication was 29.5% with a 90-day mortality rate of 1.4%.</p> <p>Conclusions - Ultrasound-directed transparenchymal application of vascular staplers to control inflow and outflow during major liver resection minimizes blood loss, warm ischemia time, and operative time compared to published reports of patients undergoing resection using other techniques.</p>	<p>346 Patients</p>	<p>Intraoperative ultrasound is used to identify major intrahepatic blood vessels and to guide the transparenchymal application of the vascular staplers.... Two firings of the stapler are usually required to completely divide the right portal vein, right hepatic artery, and right hepatic duct, as well as intervening parenchyma, leading to immediate devascularized demarcation of the right lobe of the liver."</p> <p>This technique requires no dissection of the hepatic parenchyma prior to application of the stapling device. The stapler divides the hepatic parenchyma adjacent to vascular and biliary structures while preventing bleeding from large intrahepatic blood vessels. The results confirm that hepatic inflow and outflow blood vessels can be safely and quickly controlled using vascular stapling devices. Major advantage of this stapling technique is rapid intrahepatic ligation and division of the vascular inflow to a lobe without prior dissection of the liver parenchyma.</p>	<p>"Ultrasound-directed transparenchymal application of vascular staplers to control inflow and outflow during major liver resection minimizes blood loss, warm ischemia time, and operative time compared to published reports of patients undergoing resection using other techniques."</p>

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Appendix 1

Proposed Labeling

Auto Suture™ ENDO GIA™ Universal Stapler
Instruction for Use (draft)

Autosuture™
ENDO GIA™ UNIVERSAL

DRAFT

Single Use Staplers

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The ENDO GIA™ UNIVERSAL and ENDO GIA™ UNIVERSAL XL staplers place two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows. The size of the staples is determined by the selection of the 2.0 mm, 2.5 mm, 3.5 mm or 4.8 mm single use loading unit (SULU). The ENDO GIA™ UNIVERSAL staplers will accommodate any of the single use loading unit sizes that are available in the 30 mm, 45 mm and 60 mm lines.

The ENDO GIA™ UNIVERSAL staplers with either the 2.0, 2.5, 3.5 single use loading unit is designed for introduction and use through a 12 mm trocar sleeve, or larger, with the use of a converter.

When using the ENDO GIA™ UNIVERSAL staplers with the 4.8 single use loading unit, it must be inserted into a 15 mm trocar sleeve. The instrument may be reloaded and fired up to 25 times in a single procedure.

NOTE: Each instrument can accommodate the 30-2.0, 2.5, 3.5 / 45-2.0, 2.5, 3.5, 4.8 / 60-2.5, 3.5, 4.8 mm SULU's.

INDICATIONS

The ENDO GIA™ UNIVERSAL staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

CONTRAINDICATIONS

1. Do not use the ENDO GIA™ UNIVERSAL 2.0 mm staples on any tissue that compresses to less than .75 mm in thickness, on any tissue that cannot comfortably compress to 1.0 mm or on the aorta.
2. Do not use the ENDO GIA™ UNIVERSAL 2.5 mm staples on any tissue that compresses to less than 1.0 mm in thickness, on any tissue that cannot comfortably compress to 1.5 mm or on the aorta.
3. Do not use the ENDO GIA™ UNIVERSAL 3.5 mm staples on any tissue that compresses to less than 1.5 mm in thickness, on any tissue that cannot comfortably compress to 2.0 mm or on the aorta.

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4. Do not use the ENDO GIA™ UNIVERSAL 4.8 mm staples on any tissue that compresses to less than 2.0 mm in thickness, on any tissue that cannot comfortably compress to 2.0 mm or on the aorta.
5. The ENDO GIA™ UNIVERSAL instrument should not be used on tissue such as liver or spleen where compressibility is such that closure of the instrument would be destructive.
6. Do not use the ENDO GIA™ UNIVERSAL stapler where adequacy of hemostasis cannot be verified visually after applications.
7. These devices are provided STERILE and are intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

WARNINGS AND PRECAUTIONS

1. Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected staple size. Careful consideration should be given to any pre-surgical treatment the patient may have undergone and in corresponding selection of staple size.
2. Always include the combined thickness of the tissue and of any staple line reinforcement material in use when choosing the proper staple cartridge.
3. When using the ENDO GIA™ UNIVERSAL instrument with a 4.8 single use loading unit, the instrument MUST be inserted into a 15 mm trocar. A smaller size trocar will not accept the 4.8 single use loading unit.
4. Always inspect the tissue thickness and select an appropriate staple size prior to application of the ENDO GIA™ UNIVERSAL stapler.
5. Always close the jaws of the ENDO GIA™ UNIVERSAL stapler prior to introducing and removing the stapler from the trocar sleeve.
6. After firing, always inspect the staple line for hemostasis. Minor bleeding may be controlled by electrocautery or manual sutures.
7. Placement of tissue proximal to the tissue stops (on the SULU) may result in stapler malfunction. Any tissue extending beyond the cut mark will not be transected.
8. When using the stapler more than once during a SINGLE surgical procedure, be sure to remove the empty ENDO GIA™ UNIVERSAL single use loading unit and reload a new one. A safety interlock is provided that prevents an empty single use loading unit from being fired a second time. Do not attempt to override the safety interlock.
9. When positioning the stapler on the application site, ensure that no obstructions, such as clips, are incorporated into the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.
10. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Prior to performance of any endoscopic procedures, consult the medical literature relative to techniques, complications and hazards.
11. A thorough understanding of the principles involved in laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and operator(s), and damage to the instrument.
12. When endoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that electrical isolation or grounding is not compromised.
13. The anvil must be completely visible, (past the trocar sleeve) prior to opening the SULU within the body cavity.

14. When using a staple line buttressing material (e.g., PERI-STRIPS® or SEAMGUARD® products), follow the instructions provided by the manufacturer of the buttress material, as performance of the stapler may be affected when using buttress materials.

15. The instrument and single use loading unit are provided STERILE and are intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

16. Do not attempt to load SULU while squeezing ring handle.

SCHEMATIC VIEW

- | | |
|--|---------------------------------|
| A) PIN | J) ALIGNMENT LOADING INDICATORS |
| B) UNLOAD/UNLOCK BUTTON | K) SHIPPING WEDGE |
| C) SHAFT | L) ANVIL |
| D) ARTICULATING LEVER | M) TISSUE STOP |
| E) ROTATION COLLAR | N) END OF STAPLE LINE |
| F) GREEN BUTTON | O) END OF CUT LINE |
| G) BLACK RETURN KNOB | P) INCREMENT MARKINGS |
| H) HANDLE | Q) LOWER CLAMP BUTTON |
| I) SINGLE USE LOADING UNIT (SULU) (30, 45, 60) | R) STAPLE CARTRIDGE |

LOADING

1. The SULU is packaged in the open position. Do not attempt to close the SULU.

WARNING: SELECT A SULU WITH THE APPROPRIATE STAPLE SIZE FOR THE TISSUE THICKNESS. OVERLY THICK OR THIN TISSUE MAY RESULT IN UNACCEPTABLE STAPLE FORMATION. ALWAYS INCLUDE THE COMBINED THICKNESS OF THE TISSUE AND OF ANY STAPLE LINE REINFORCEMENT MATERIAL IN USE WHEN CHOOSING THE PROPER STAPLE CARTRIDGE.

CAUTION: Do not attempt to remove the shipping wedge until the SULU is loaded into the instrument.

2. Ensure that the black knobs on the instrument are pulled back completely and the articulation arm is neutral to the instrument.

G) BLACK RETURN KNOBS

3. To load the ENDO GIA™ UNIVERSAL stapler with the appropriate SULU, insert the pin located at the distal end of the instrument shaft into the SULU. Ensure that the white LOAD alignment indicator on the SULU aligns with the white LOAD alignment indicator on the shaft. Push the SULU in and twist clockwise 45° relative to the instrument, so that the SULU will lock into place. The white LOAD indicator on the instrument shaft will align with the white LOAD indicator on the SULU.

J1) WHITE LOAD ALIGNMENT INDICATOR (SULU)

J2) WHITE LOAD ALIGNMENT INDICATOR (SHAFT)

4. Remove the shipping wedge from the SULU prior to inserting the instrument into the trocar.

CAUTION: Do not clamp instrument prior to removing shipping wedge.

5. To confirm proper loading, cycle the instrument after loading the SULU. Squeeze the handle once to close the jaws of the SULU. Pull back on the black return knobs and confirm that the SULU jaws open fully.

UNLOADING

1. To unload a SULU from the stapler, the articulating lever must be in the neutral position. Ensure that the jaws of the SULU are open by pulling the black return knobs back completely. Pull the UNLOAD/UNLOCK button (located on the underside of the

shaft) back towards the instrument, twist the SULU counterclockwise 45° and remove the SULU from the shaft of the instrument.

D) ARTICULATING LEVER

B) UNLOAD/UNLOCK BUTTON

INSTRUCTIONS FOR USE

NOTE: The jaws of the SULU must be closed prior to introducing the instrument into the trocar sleeve. To do so, squeeze the handle.

1. Insert the ENDO GIA™ UNIVERSAL stapler into an appropriately sized trocar sleeve, or larger, with the use of a converter.

CAUTION: The anvil must be completely visible, (past the trocar sleeve) prior to opening the SULU within the body cavity.

The instrument shaft rotates 360° and articulates 22° and 45° in both directions with use of articulating lever.

NOTE: When using the ENDO GIA™ UNIVERSAL instrument with a 4.8 single use loading unit, the instrument MUST be inserted into a 15 mm trocar. A smaller size trocar will not accept the 4.8 SULU.

2. Once inside the body cavity, open the jaws of the instrument by pulling the black return knobs completely back.

CAUTION: Do not squeeze the instrument handle while pulling back the black knobs.

3. Apply the ENDO GIA™ UNIVERSAL stapler across the tissue to be transected.

Caution: Ensure that no obstructions (such as clips) are incorporated in the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.

The instrument will not cut tissue beyond the black cut mark indicated on the single use loading unit. More than one application of the ENDO GIA™ UNIVERSAL stapler may be necessary for tissue exceeding the length of the SULU (30 mm, 45 mm or 60 mm).

S) CUTMARK

CAUTION: Placement of tissue proximal to the tissue stops (on the SULU) may result in stapler malfunction. Any tissue extending beyond the cut mark will not be transected.

4. Close the jaws of the instrument across the tissue to be transected by squeezing the handle completely. The stapler is equipped with a safety interlock; the instrument will not fire the staples and cut tissue unless the green button is pushed.

CAUTION: A safety interlock is provided that prevents an empty single use loading unit from being fired a second time. Do not attempt to override the safety interlock.

The jaws of the instrument may be repositioned on the tissue prior to firing by pulling the black return knobs completely back, allowing the jaws to open.

5. In order to fire the instrument, push the green button. Squeeze the handle sequentially until the oval clamp cover reaches the distal end of the cartridge slot, and the handle locks.

Sequential squeezes of the handle are required to fully fire the SULU.

The total number of squeezes is relative to the length of the SULU (30, 45 or 60).

FAILURE TO COMPLETELY FIRE THE SULU WILL RESULT IN AN INCOMPLETE CUT AND/OR INCOMPLETE STAPLE FORMATION, WHICH MAY RESULT IN POOR HEMOSTASIS.

F) GREEN BUTTON

Q) LOWER CLAMP BUTTON

6. Once the instrument has been completely fired, pull the black return knobs completely back, releasing the tissue from the jaws. Gently remove the instrument from the tissue. The site should be checked for hemostasis following removal of the instrument. Minor bleeding may be controlled using electrocautery or manual sutures.

8. After completely firing the SULU, close jaws of the instrument and remove the ENDO GIA™ UNIVERSAL stapler from the body cavity to unload the single use loading unit from the instrument.

NOTE: Do not attempt to insert or remove the instrument from the trocar sleeve if the instrument is in the articulated position.

The ENDO GIA™ UNIVERSAL may be reloaded and fired up to 25 times in a single procedure.

STAPLE SPECIFICATIONS

T) INSTRUMENT REORDER CODES

W) COLOR

U) SULU REORDER CODES

X) OPEN STAPLE SIZE

V) STAPLE LINE LENGTH

Y) CLOSED STAPLE SIZE

SEAMGUARD® , is a registered trademark of W.L. Gore & Associates, Inc.

PERI-STRIPS® , is a registered trademark of Bio-Vascular, Inc.

STORE AT ROOM TEMPERATURE.

AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

DO NOT EXPOSE TO TEMPERATURES ABOVE 130° F (54° C).

Appendix 2

Product Brochure

Auto Suture™ ENDO GIA™ UNIVERSAL Stapler



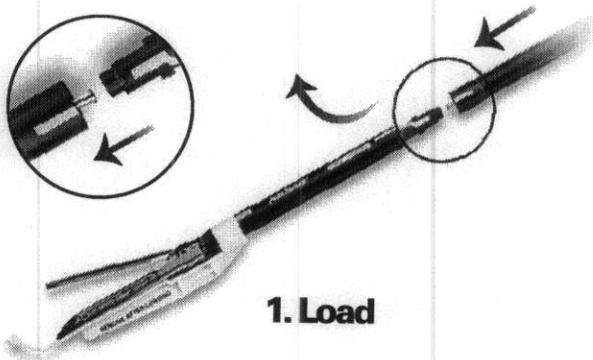
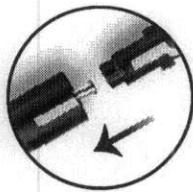
Superior Line Staple Security!

ENDO GIA[®] Universal Stapling System

30, 45 or 60 mm Straight and Rotulating Loading Units, All with 6 Rows of Staples

ENDO GIA* Universal Stapler System

Load



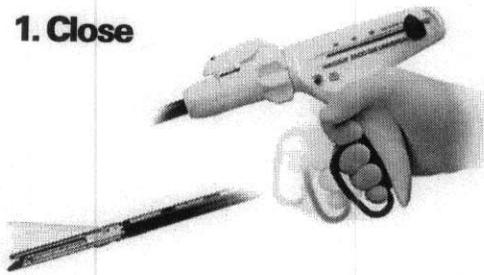
1. Load



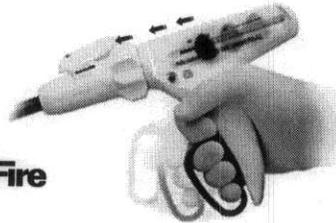
2. Remove Shipping Wedge

Fire

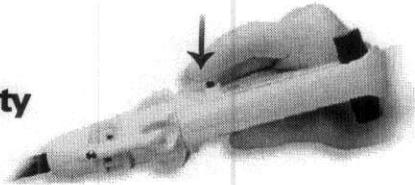
1. Close



3. Fire



2. Push Safety



4. Open

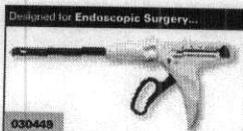
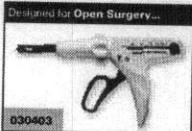
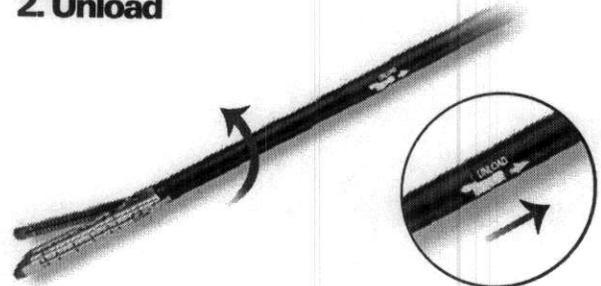


Unload

1. Open



2. Unload



ENDO GIA® II STRAIGHT SULUS	
030416	(2.0)
030418	(2.5) 30 mm
030419	(3.5)
030426	(2.0)
030425	(2.5) 45 mm
030422	(3.5)
030423	(4.8)
030412	(2.5) 60 mm
030414	(3.5)
030415	(4.8)

ENDO GIA® ROTICULATING SULUS	
030450	(2.0)
030451	(2.5) 30 mm
030452	(3.5)
030453	(2.0)
030454	(2.5) 45 mm
030455	(3.5)
030457	(2.5) 60 mm
030458	(3.5)

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Healthcare

Appendix 3
Relevant Clinical Literature
Prospective and Retrospective Studies
Full articles

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An initial experience and evolution of laparoscopic hepatic resectional surgery

Joseph F. Buell, MD, Mark J. Thomas, MD, Travis C. Doty, BSN, Keith S. Gersin, MD, Todd D. Merchen, MD, Manish Gupta, MD, Steven M. Rudich, MD, and E. Steve Woodle, MD, Cincinnati, Ohio

Background. The use of minimally invasive procedures has revolutionized modern surgery. Only recently has laparoscopy been introduced for use in hepatic surgery.

Methods. Patient demographics, tumor characteristics, and outcomes were evaluated for all initial cases of laparoscopic hepatic resection.

Results. Twenty-one resections were performed in 17 patients; 5 were performed for malignancy, of which 3 had underlying cirrhosis, and the remaining 12 for benign symptomatic disease. Mean patient age was 55.4 (range, 24-82 years). The mean number of lesions was 1.4 (range, 1-5), having an average size of 7.6 cm (range, 2-30 cm). Mean operative time was 2.8 hours (range, 2-5 hours) hours. Most resections involved 1 or more Couinaud segments. Mean blood loss was 288 cc (range, 50-150 cc).

Complications included re-operation for hemorrhage ($n = 2$), biliary leakage ($n = 1$), and death from hepatic failure ($n = 1$). Mean length of stay was 2.9 days (range, 1-14). When compared with our series of 100 patients who underwent open hepatic resection for benign tumors, significantly greater means ($P < .05$) were noted for blood loss (485 cc), operative time (4.5 hours), and length of stay (6.5 days).

Conclusions. Laparoscopic hepatic surgery, though complex, can be performed safely and efficaciously. Minimally invasive surgery appears to provide several distinct advantages over traditional open hepatic surgery. However, techniques for the laparoscopic control of bleeding and bile leak remain in their infancy. (Surgery 2004;136:804-11.)

From the Division of Transplantation, University of Cincinnati, Cincinnati, Ohio

IN THE LAST TWO DECADES, the introduction of laparoscopic techniques has revolutionized general surgery. Minimally invasive surgery, which often yields a reduction in postoperative pain and disability, has proven successful in decreasing length of hospital stays and reducing patient recovery time.¹ Initial experiences with laparoscopic cholecystectomy were met with skepticism. Criticism of this procedure was justified by observations of significant increases in bile duct injuries associated with the proliferation of this procedure. These observations challenged the surgical community to establish minimal competency requirements and develop practice guidelines for its use.

The most recent and advanced laparoscopic innovations have centered on their use in the performance of solid organ surgery, including partial nephrectomy, prostatectomy, and hepatic resection. Performance of laparoscopic non-anatomic wedge biopsies was first reported in the early 1990s.² This technique was incorporated and reported in the performance of a small series of laparoscopic staging procedures for lymphoma.

Concurrently, during the last 2 decades, open hepatic surgery has also enjoyed a period of significant advances. Morbidity as well as mortality rates has dramatically declined from 25% to less than 5%.³ These improvements arose from advances in the fields of anesthesia and critical care, and an increased understanding of intrahepatic vascular anatomy based on Couinaud segments. To date, attempts at laparoscopic hepatic surgery have highlighted several issues including: (1) laparoscopic hepatic resection is a procedure that is recommended for groups with expertise in both laparoscopy and hepatic surgery; (2) control of hemorrhage has proven challenging; and (3) the oncologic integrity of this operation remains

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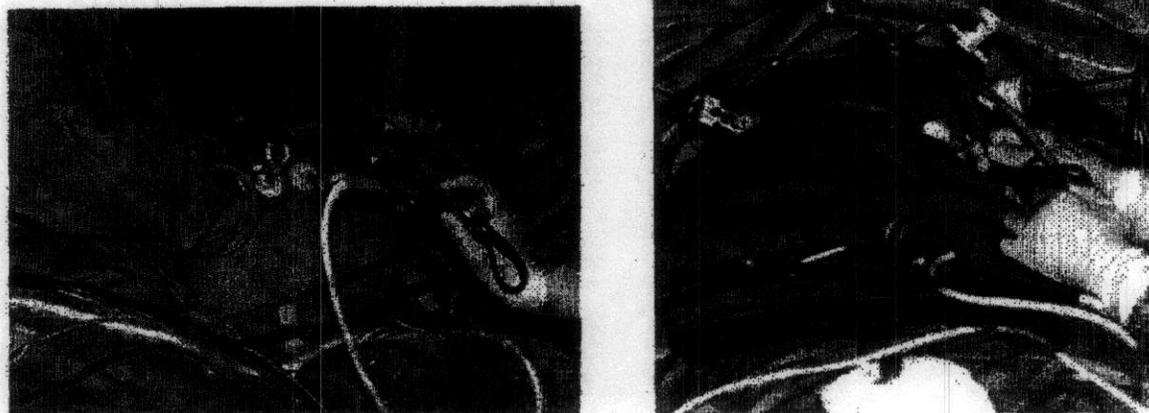


Fig 1. Port and LapDisc (Ethicon) placement.

unproven. During the period of initial reports, the greatest concern of surgeons centered on the risk of air embolism under pneumoperitoneum during hepatic vein division. This risk led several groups to explore and develop several alternative techniques, including the use of inert gas and gasless laparoscopy.^{4,7} Perhaps because of these concerns, few centers have pursued and/or have reported on sizable series of patients who have undergone laparoscopic hepatic resections or hepatectomies. Herein, the authors present their initial experience with laparoscopic hepatic resection with a critical assessment of patient selection and operative techniques.

METHODS

In 2002, the authors initiated a laparoscopic hepatic resection program at the University of Cincinnati Hospital. The hepatobiliary group comprises surgeons trained in advanced laparoscopic techniques, hepatobiliary surgery, and liver transplantation, and performs over 250 liver transplant and/or hepatobiliary cases annually. Candidacy for hepatic resection was determined solely by the anatomic positioning of tumors in association with the vena cava and major hepatic vascular structures (hepatic vein confluence and portal bifurcation). Before the introduction of laparoscopic hepatic resection, our group had acquired extensive experience performing laparoscopic nephrectomy,

tumor staging, and radiofrequency ablation, with the later routinely performed in both cirrhotic and noncirrhotic patients of Child's A through C classifications. Thus, the indication for laparoscopic hepatic resection of patients with hepatocellular cancer (HCC) included the presence of peripheral tumors and any Child's classification.

At the time of this report, 17 (24%) of 70 patients evaluated were candidates for laparoscopic surgery. Laparoscopic liver resection was performed in a supine position, by using a beanbag for stabilization and support. Patients with right posterior lesions or large right lobe hepatic cysts greater than 10 cm were propped up on their right side via a beanbag. Using a Hasson technique, an infraumbilical 10-mm port is inserted. The abdomen is then insufflated to a pressure between 18 and 20 mm Hg. Subsequent port placement used 10- and 12-mm, low-profile balloon port trocars (Tyco Healthcare, Norwalk, Conn) to minimize port intrusion on the assistant's hand, which would be introduced through the placement of the LapDisc (Ethicon, Cincinnati, Ohio) hand-assist port. A 4-port configuration was based on the presence of a left- or right-sided lesion (Fig 1). After laparoscopic examination of the peritoneal cavity and porta hepatis, the liver was intraoperatively evaluated with the aid of a laparoscopic ultrasound probe. Once the number and location of hepatic lesions were confirmed, the falciform

Table 1.
Postoperative complications, morbidity, and mortality after stapler hepatectomy

	Total		Major hepatectomy		Minor hepatectomy	
	n = 300	100%	n = 193	100%	n = 107	100%
Surgical complications ^a	65	21.7	52	26.9	13	12.2
Bile leak/bilioma	24	8.0	22	11.8	2	1.8
Wound infection	9	3.0	7	3.7	2	1.8
Pneumothorax (chest tube)	7	2.3	6	3.2	1	0.9
Abscess (abdominal cavity)	6	2.0	4	2.1	2	1.8
Bleeding ^b	5	1.7	4	2.1	1	0.9
Perforation of the colon	3	1.0	2	1.1	1	0.9
Abscess (liver)	2	0.7	2	1.1	0	0
Dehiscence of abdominal wall closure	1	0.3	1	0.5	0	0
Partial liver necrosis	1	0.3	0	0	1	0.9
Other	14	4.7	10	5.4	4	3.5
Medical complications ^a	54	18.0	42	21.8	12	11.2
Pleural effusion (chest tube)	20	6.7	17	9.1	3	2.7
Renal insufficiency ^c	14	4.7	10	5.4	4	3.5
Cardiac insufficiency	8	2.7	6	3.2	2	1.8
Sepsis	5	2.0	4	2.1	1	0.9
Liver failure	5	1.7	5	2.7	0	0
Pneumonia	4	1.3	3	1.6	1	0.9
Cholangitis	3	1.0	3	1.6	0	0
Myocardial infarction	1	0.3	0	0	1	0.9
Lower GI hemorrhage	1	0.3	0	0	1	0.9
Urinary tract infection	1	0.3	1	0.5	0	0
Multi-organ failure	1	0.3	1	0.5	0	0
Morbidity ^a	99	33.0	77	39.9	22	20.6
Relaparotomy	20	6.7	16	8.3	4	3.7
Mortality	13	4.3	10	5.2	3	2.8

^aFor patients with ≥ 1 complications.

^bFor patients with a blood loss >300 ml/hour.

^cFor patients with a creatinine >2 U/ml.

the subphrenic and subhepatic space and the abdomen was closed. In this method of liver resection no Pringle's maneuver or other vascular control was necessary in 90% of the patients.

Assumptions Made for Cost Analysis

The potential costs based on median values of requirements of an average case of stapler hepatectomy were calculated (Table 2). For cost analysis, we made certain assumptions. All surgical procedures required general anesthesia. The cost of the preoperative evaluation and follow-up was identical for the various procedures, and thus it was excluded from analysis. The cost of postoperative complications was excluded from analysis because complication rates after liver resection were low, rendering complication costs inconsequential in the model. Further, other treatment costs were negligible in the model.

Statistics

SAS software (Release 9.1, SAS Institute, Inc., Cary, NC, USA) was used for statistical analysis. In this study end points considered were postoperative surgical morbidity and hospital mortality. Logistic regressions were performed for univariate and multivariate analysis to assess the impact of the following dichotomized variables on the study end points: age (70 years), gender, blood loss (1200 ml), operative time (180 minutes and 300 minutes), indication (primary malignancy of the liver), type of resection (major hepatectomy), and extrahepatic resection (yes). The relative risk was described by the estimated odds ratio (OR) with a 95% confidence interval (CI). To analyze the impact of blood loss and operative time on the study end points, the first and third quartiles were used to divide patients into groups.

Comparisons of subgroups of patients with operative time (180 minutes and 300 minutes) and type of resection (minor and major) were analyzed with Fisher's exact test.

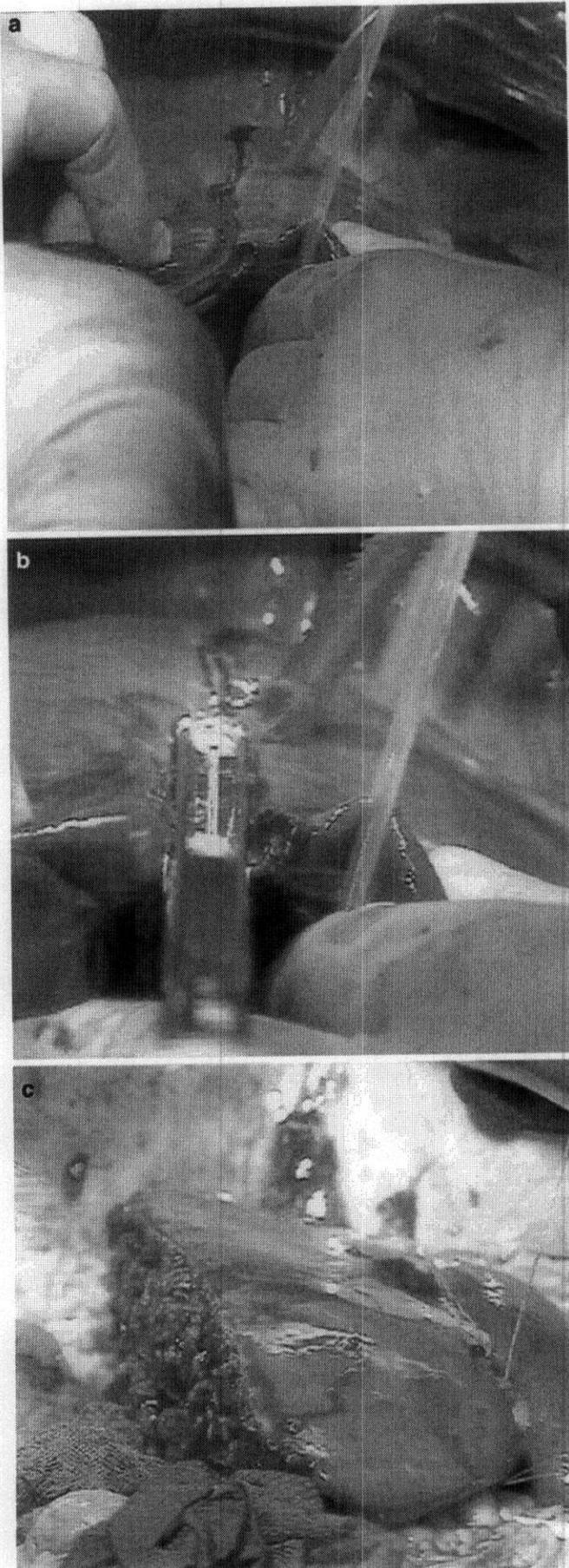


Figure 1. A. After marking the transectional line, the liver capsule was divided with diathermy. For subsequent dissection of the hepatic parenchyma, the liver tissue was fractured stepwise with a vascular clamp. B. Transection and division of the hepatic parenchyma was performed with endo GIA vascular staplers. C. After completed resection, the dissectional plane usually did not show major oozing or leakage of bilious fluid.

The quantitative parameters operative time, blood loss, and hospital stay were analyzed with respect to type of resection using the Mann-Whitney *U*-test. Descriptive statistics are presented as median with interquartile range (IQR: 25%–75%). Two-sided *P* values were always computed, and an effect was considered statistically significant with $P < 0.05$.

RESULTS

Demographics

A series of 300 patients who underwent stapler hepatectomy for various hepatic tumors and other reasons from October 1, 2001, to January 31, 2005, comprised 164 (55%) men and 136 (45%) women (Table 3). These patients had a median age of 62 years (Table 3). During the same period another 116 patients, 61% male and 39% female, underwent conventional liver resection. These patients were comparable with the stapler group based on a median age of 64.5 years.

Indication for Liver Resection

The diagnoses of patients in the stapler group are listed in Table 3; 14% of patients resected with staplers had benign lesions and 79% had malignant liver tumors. Of latter patients 72% were metastatic, where all but 60 (35%) spread from a colorectal tumor. The distribution of the underlying diagnosis for resection in the conventionally resected group was comparable to the stapler group ($P = 0.514$), with 13% ($n = 15$) benign lesions, 17% ($n = 20$) primary malignant liver tumors, 9% ($n = 10$) other tumors, and 61% ($n = 71$) malignant tumors which were metastatic, where all but 23 spread from a colorectal tumor.

Surgical Procedures

The procedures performed are listed in Table 3. Major and minor liver resection were defined as described recently.²⁷ There were 193 (64%) major resections (i.e., removal of three segments or more) and 107 minor hepatic resections. Patients underwent hemihepatectomy

Table 2.
Cost analysis in Euro

Stapler hepatectomy (intraoperative costs)	
Endo GIA vascular staplers ^a	1039
Blood products (FFP + RBC) ^b	
Department of Surgery (€16.40/minute) ^b	3444
Department of Anesthesiology (€3.40/minute) ^b	714
<i>Subtotal</i>	<i>5197</i>
Hospital stay	4928
ICU stay	1257
<i>Subtotal</i>	<i>6185</i>
Total	11,382

^aAn average of seven endo GIA vascular stapler magazines (Tyco 030412, 60 cm) plus one hand set (Tyco 030403) used per resection.

^bMedian values for units of transfused blood products and operative time have been used for calculation.

FFP: fresh frozen plasma; RBC: red blood cells; ICU: intensive care unit.

or extended hemihepatectomy in 37% and 17% of the cases, respectively. Further, 30 patients (10%) underwent resection of ≥ 3 segments other than (extended) hemihepatectomy. Minor resection have been performed in 36% of cases. These patients underwent resection of one segment (36%), a segmental resection consisting of either an en bloc resection (56%) of two segments or a resection of two discontinuous segments (8%). Forty-seven percent ($n = 55$) of the conventionally resected patients underwent liver resection with CUSA. The liver parenchyma of all other patients ($n = 61$) were resected with various methods, such as electric knife, scalpel, scissors, high frequency coagulation, bipolar forceps, or blunt dissection. In contrast to the stapler group, patients underwent lobectomy or extended lobectomy in 21% ($n = 24$) and 8% ($n = 9$) of the cases, respectively. Further, there were significantly more minor hepatic resections (63%) and fewer major liver resections (37%) performed in the patients resected conventionally, as compared with 36% and 64%, respectively, in the stapler resection group ($P < 0.0001$).

Operative Time, Intraoperative Hemorrhage, and Blood Transfusion

Intraoperative data are presented in Table 4. The median operative time of all liver resections with transection of hepatic parenchyma using endo GIA vascular staplers was 210 minutes. Analysis of major and minor hepatectomy revealed that operative time was 240 minutes and 155 minutes, respectively ($P < 0.0001$). In all patients a median blood loss of 700 ml was recorded during stapler hepatectomy. While during major liver

Table 3.

Demographics, indications and type of resection of patients who underwent stapler hepatectomy

Characteristics	n = 300	100%
Median age (years)	61.7	IQR: 52.3–68.3
Male/female	164/136	54.7/45.3
Primary malignant	67	22.4
Hepatocellular carcinoma (HCC)	35	11.7
Cholangiocellular carcinoma (CCC)	32	10.7
Metastatic	170	56.7
Colorectal	110	36.7
Other	60	20.0
Benign	43	14.3
Adenoma	7	2.3
FNH	13	4.3
Cysts	6	2.0
Echinococcus	6	2.0
Others	11	3.7
Gallbladder carcinoma	5	1.7
Other tumor	15	5.0
Major hepatectomy	193	64.3
Right hemihepatectomy	82	27.3
Extended right hemihepatectomy	39	13.0
Left hemihepatectomy	29	9.7
Extended left hemihepatectomy	13	4.3
Segmentectomy ($n \geq 3$) ^a	30	10.0
Minor hepatectomy	107	35.7
Segmentectomy ($n = 1$)	44	14.7
Segmentectomy ($n = 2$) ^b	63	21.0
Concomitant extrahepatic resection ^c	44	14.7

^aResection of three or more segments other than (extended) hemihepatectomy.

^bSegmental resection consisting of either an en bloc resection or resection of two discontinuous segments.

^cThe following visceral organs have been resected in addition to liver tissue (gallbladder excluded): small bowel ($n = 16$), colorectal ($n = 15$), stomach ($n = 14$), pancreas ($n = 11$).

resection blood loss was 800 ml, only 500 ml blood loss was recorded during minor hepatectomy ($P < 0.0001$). Eighty-three percent and 89% of all patients obtained no intraoperative RBC and FFP transfusion during surgery, respectively. In patients who required transfusion during liver resection a median of 3 units RBC (IQR: 2–6 units; $n = 52$ patients) and 4 units FFP (IQR: 3–6 units; $n = 37$ patients) were given. Subgroup analysis of both major and minor hepatectomy indicated there was no difference in RBC transfusion and FFP infusion.

ICU and Hospital Stay

Both the median values of the postoperative stay on the ICU and the postoperative hospital stay (Table 4), were significantly increased from a median of 1 and 10

Table 4.
Perioperative parameters during liver resection ($n = 300$)

Perioperative parameters	Total		Major hepatectomy		Minor hepatectomy	
	n = 300		n = 193		n = 107	
Operative time (minutes) ^a	210	IQR: 155–292.5	240	IQR: 180–300	155	IQR: 120–245
Blood loss (ml) ^a	700	IQR: 350–1200	800	IQR: 500–1500	500	IQR: 200–800
RBC transfusion	n = 52	17.3%	n = 36	18.7%	n = 16	15.0%
FFP infusion	n = 37	11.0%	n = 27	14.0%	n = 10	9.4%
ICU stay > 2 days	n = 53	17.7%	n = 43	22.3%	n = 10	9.4%
Postoperative hospital stay (days) ^a	10	IQR: 8–14	11	IQR: 9–16	9	IQR: 7–11

^aMedian values with interquartile range (IQR) are given.

days to 2 and 18 days, respectively, in patients who developed surgical complications after stapler hepatectomy ($P < 0.0001$). Thirty-seven percent of patients with surgical complications stayed more than 2 days on the ICU, compared to only 12% of the patients without complications. While 18% of all patients stayed on the ICU for > 2 days, subgroup analysis of patients who underwent minor resection revealed that the percentage of these patients staying for > 2 days in the ICU after major resection was only 42% of patients ($P = 0.0045$). Further, the median hospital stay was reduced by 18% (2 days) after minor resection compared with major hepatectomy ($P < 0.0001$).

Mortality and Morbidity

There were 13 deaths after stapler hepatectomy, for a perioperative mortality rate of 4% (Table 1). Four of the 13 patients who died after liver resection underwent extended right hemihepatectomy and 5 patients died after right hemihepatectomy (Table 5). Four patients died after segmental resection due to pulmonary insufficiency ($n = 1$), myocardial infarction ($n = 1$), and sepsis ($n = 2$) due to peritonitis or intra-abdominal abscess (Table 5). Two of the latter four patients underwent an additional extrahepatic resection (Table 5).

At least one of two medical and surgical postoperative complications occurred in 33% ($n = 99$) (Table 1) of patients. After stapler hepatectomy, pleural effusion was the most frequent therapy-relevant medical complication, with 7% of all cases (Table 1). Twenty-five percent of patients with pleural effusion and all patients with pneumothorax required drainage after stapler hepatectomy. Of the 24 patients who developed a bile leakage or bilioma, only four patients required re-laparotomy; all other patients were either treated conservatively or interventionally. Three of the 6 patients with a postoperative abscess in the abdominal cavity were successfully treated non-

operatively by interventional drainage. Further indications for a re-laparotomy were postoperative hemorrhage ($n = 5$), wound infection ($n = 2$), liver abscess ($n = 1$), and ischemic perforation of the colon ($n = 1$).

Moreover, in 4 patients with multi-organ failure and sepsis, an exploratory laparotomy was performed. Analysis of both major and minor hepatectomy groups clearly indicated that there was a significant difference between groups for the number of surgical complications. While in 27% of patients a complication occurred after major resection, this number decreased to 12% after minor hepatectomy (Table 1) ($P = 0.0032$). This significant difference was especially true for the incidence of a bile leak / bilioma ($P = 0.0016$). The morbidity in both major and minor hepatectomy groups were 40% and 20% of cases, respectively (Table 1) ($P = 0.00081$).

Risk Factors for Surgical Morbidity

Univariate analysis revealed that patients with a blood loss of ≥ 1200 ml ($P = 0.0012$), operative time of >180 minutes ($P < 0.0001$), primary malignant liver tumor ($P = 0.0006$), and major hepatectomy ($P = 0.0037$) had a significantly increased risk for the development of surgical complications (Table 6). Patient age, gender, and concomitant extrahepatic resection had no impact on the risk for surgical complications (Table 6).

Multivariate analysis confirmed the operative time of ≥ 180 minutes ($P = 0.0003$), ≥ 300 minutes ($P < 0.0001$), and primary malignancy ($P = 0.0003$) as risk factors for the development of surgical complications. Intraoperative blood loss per se and type of resection had an impact on the univariate analysis. However, this was not confirmed by multivariate analysis (Table 7). Major hepatectomy was the most time-consuming procedure with a duration of >180 minutes in 79% of cases (Fig. 2a). There was no significant increase in the number of patients with a blood

Table 5. Mortality—patient characteristics, operation, and complications

	Sex	Age	Diagnosis	Type of resection	Extrahepatic resection (other than gallbladder)	Blood loss (ml)	Operative time (min)	ICU (days)	Complications	Day of re-laparotomy	Day of death
Major resection	F	78	Gallbladder carcinoma	Right hepatectomy	Biliodigestive anastomosis, partial portal vein resection	4000	480	1	Cardiac insufficiency, pulmonary insufficiency	—	6
	M	70	CCC	Right hepatectomy	—	3500	370	61	Sepsis	5	61
	M	60	Metastasis (pancreatic)	Right hepatectomy	—	3500	175	10	Bleeding, sepsis, pleural effusion, cardiac insufficiency	1	10
	M	40	Metastasis (testicular)	Right hepatectomy	—	500	365	3	Sepsis, ileus, cardiac insufficiency	3	3
	M	61	Hepatic abscess	Right hepatectomy	Biliodigestive anastomosis	400	358	22	Bleeding, bilioma	9	22
	F	72	Gallbladder carcinoma	Extended right hepatectomy	Biliodigestive anastomosis, partial duodenectomy	1600	235	52	Renal insufficiency, pneumonia,	7	52
	M	52	Metastasis (colorectal)	Extended right hepatectomy	—	1500	240	4	multi-organ failure Pleural effusion, ischemic perforation of the colon, abscess	7	25
	M	72	Metastasis (colorectal)	Extended right hepatectomy	Diaphragm	750	180	14	Renal insufficiency, pneumonia, abscess (abdominal cavity)	14	14
	M	68	CCC	Extended right hepatectomy	Multi-organ resection (partial resection of both stomach and duodenum, Biliodigestive anastomosis, lymphadenectomy, common bile duct resection	1100	575	33	Bilioma, sepsis	12	33
	M	76	HCC	Tri-segmental resection (S5,S6,S8)	—	1600	285	1	Pleural effusion, abscess (abdominal cavity)	14	23
Minor resection	M	54	Metastasis (esophageal)	Segmental resection (S2)	Esophageal resection (thoracotomy)	1200	360	8	Pulmonary insufficiency	—	27
	M	53	HCC	Segmental resection (S6)	—	50	140	1	Wound infection, sepsis, perforation of colon and duodenum, pleural effusion	15	27
	M	77	HCC	Segmental resection (S4b)	—	1000	90	3	Myocardial infarction	—	3

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Table 6.
Results from univariate logistic regression analyses of variables potentially associated with surgical morbidity after stapler hepatectomy (n = 300)

Variables	Events/n	Odds ratio	95% Confidence interval	p Value
Age				
<70 years	51/240	1		
≥70 years	14/60	1.13	0.56–2.17	0.7262
Gender				
Male	40/164	1		
Female	25/136	0.70	0.39–1.22	0.2099
Blood loss				
<1200 ml	36/215	1		
>1200 ml	29/85	2.58	1.45–4.57	0.0012
Operative time				
<180 minutes	7/102	1		
180 min–<300 minutes	31/125	4.48	1.98–11.52	<.0001
≥300 minutes	27/73	7.97	3.39–21.10	<.0001
Indication				
Other indication	40/233	1		
Primary malignant	25/67	2.87	1.57–5.23	0.0006
Type of resection				
Minor hepatectomy	13/107	1		
Major hepatectomy	52/193	2.67	1.46–5.36	0.0037
Concomitant extrahepatic resection				
No	51/256	1		
Yes	14/44	1.87	0.91–3.74	0.0802

Table 7.
Results from multivariate logistic regression analysis (final model) of variables associated with surgical morbidity after stapler hepatectomy (n = 300)

Variables	Odds ratio	95% Confidence interval	P Value
Operative time			
≥180 min versus <180 minutes	5.22	2.25–13.74	0.0003
≥300 min versus <180 minutes	8.68	3.61–23.55	< 0.0001
Indication			
Primary malignant versus other	3.33	1.74–6.41	0.0003

loss of ≥1200 ml between an operative time of 180–360 minutes and ≥360 minutes (Fig. 2c). However, with a decrease in operative time, fewer patients with a blood loss of <1200 ml were observed, whereas the number of patients with a blood loss ≥1200 ml increased significantly with an operative time of >180 minutes (Fig. 2c). Thus, both blood loss and type of resection have a strong correlation with operative time ($P < 0.0001$). Furthermore, primary malignancy of the liver is a risk factor for surgical complications that is independent of operative time (Fig. 2b) ($P = 0.3691$).

Both univariate and multivariate analysis revealed that patients older than 70 years of age ($P = 0.0448$) and patients with an intraoperative blood loss of ≥1200 ml ($P = 0.0273$) had an increased risk for death within the postoperative phase.

Cost Analysis in Euro (€)

For stapler hepatectomy the intraoperative costs, including surgery, anesthesiology, blood products, and the average number of endo GIA vascular staplers (Tyco 030412, 60 cm; Tyco 030403, hand set) used, added up to €5197, reflecting the intraoperative costs influenced by the resection technique. The median hospital stay (€4928) and ICU stay (€1257) add up to a total of €11,382. An internal matched-pair analysis of 78 patients undergoing liver resection with endo GIA vascular staplers and 78 historic patients who underwent conventional liver resection with CUSA before October 2001 was carried out. Patients who underwent a multivisceral resection were excluded to eliminate influences unrelated to liver resection. On average, there was a cost benefit of more than

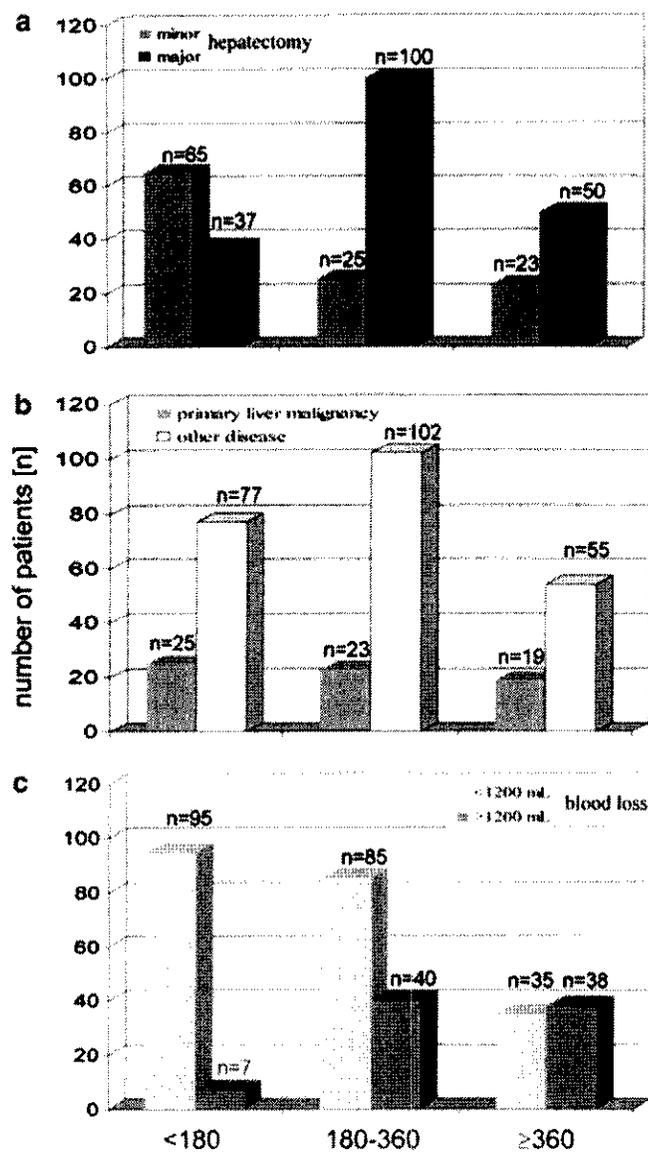


Figure 2. Type of resection, primary malignancy of the liver, and blood loss after stapler hepatectomy. To analyze the impact of type of resection, blood loss (<1200 ml, ≥1200 ml), and primary malignancy of the liver on the operative time. Distribution of patients in the categories <180 minutes, 180–360 minutes, and ≥360 minutes for operative time after both minor and major hepatectomy ($P < 0.0001$) (A), primary malignancy of the liver ($P = 0.3691$) (B), and blood loss ($P < 0.0001$) (C).

€2400 when comparing the two methods that favored stapler hepatectomy (data presented at the 6th Congress of the European Hepato-Pancreato-Biliary Association).

DISCUSSION

Recent publications reporting a number of techniques using stapling devices in liver surgery showed them to be extraordinarily helpful in the safe ligation of inflow and

outflow vessels.^{7,8,18–23} The use of vascular staplers to divide hepatic veins¹⁸ and portal branches, is considered an achievement that has aided in minimizing blood loss and thereby reducing the need for inflow occlusion. Most recently, an ultrasound-directed application of vascular staplers to selectively divide major intrahepatic blood vessels for inflow and outflow control during major liver resection has been shown to achieve excellent results, reducing blood loss, warm ischemia time, and operative time.²⁵ Furthermore, reports of left lateral segmentectomies performed with stapler and stapled wedge resections of the liver also showed favorable results.^{18,23,24}

Wedge resections at the edges of the liver, which can be performed adequately with laparoscopy and the stapler, seem to be advantageous in the unroofing of hepatic cysts, because any inadvertently injured bile duct or blood vessel is sealed. Stapling devices can also be useful in patients with coagulopathy and in the treatment of complex liver abscesses.^{19–21,23,28} However, no large series of stapler use for the phase of parenchymal transection for liver resection have been published. Thus, our series of 300 patients who underwent stapler hepatectomy were documented prospectively to elucidate whether this technique for parenchymal dissection is applicable in a routine clinical setting based on both its feasibility and its safety, with its associated surgical risk factors for the development of postoperative complications to index considerable feasibility and early postoperative outcome.

Indeed, in our hands, parenchymal transection with endo GIA vascular staplers is a feasible and safe technique for liver resection. In the present nonselective series both mortality (4%) and morbidity (33%) were as low as in recently published large series of nonselected patients who underwent liver resection in other high-volume surgical centers.^{27,29–31} Control of operative blood loss is one of the most immediate concerns when performing liver resection. The detrimental impact of excessive hemorrhage and blood transfusion of patients undergoing liver resection is well documented. Excessive blood loss is associated with increased perioperative morbidity and, in cases of colorectal metastases, a shorter disease-free interval.^{32,33} In contrast to most series,^{27,29,30} only 10% of our patients were subjected to the Pringle maneuver, and no other vascular control was applied during resection. Median blood loss was 700 ml (major resection: 800 ml, minor resection: 500 ml) during stapler hepatectomy. Jamagin *et al.* reported a median blood loss of 600 ml; however, resection of ≥3 segments comparable to major hepatectomy in their study led to a blood loss of more than 1000 ml, in contrast to 800 ml in

the present study.²⁷ Further, series comprising of $\geq 70\%$ cases of hepatic vascular exclusion-aided major hepatectomy reported a median blood loss between 1000 and 1325 ml.³⁴ Similar values were reported for blood loss during liver resection with portal triad clamping or extrahepatic control of the hepatic veins.^{31,35} As a consequence, transfusion of blood products was required in up to 50% of cases.^{31,35} More recent studies reported 750 ml as median intraoperative blood loss, and about 17% of their patients required transfusion. However, again 27% of these patients underwent the Pringle maneuver during liver resection.³⁰ A further decrease in intraoperative blood loss can be achieved with selective transhepatic division of major intrahepatic blood vessels as inflow and outflow control before dissection of the liver parenchyma.²⁵ However, it has been reported that hepatic vascular exclusion is associated with unpredictable hemodynamic intolerance and increased postoperative complications with longer hospital stay, and should be restricted to lesions involving the cavo-hepatic intersection.³⁵ The extended Pringle maneuver itself may be associated with complications resulting from ischemic injury of the remnant liver and from abdominal visceral venous stagnation.³⁶ In our series no RBCs and FFPs were transfused in 84% and 89% of cases. Patients who required transfusion a median of 3 units RBC and 4 units FFP were given.

Biliary leakage and biliomas present as major obstacles after liver resection. While the overall complication rate markedly decreased, the incidence of bile leakage still occurs frequently. In our series a bile leak or bilioma was recorded in 8% of cases, a finding consistent with data of previous reports.³⁷

The median operative time was 210 minutes in all patients (Table 4). For major hepatectomy a median time of 240 minutes was required while minor liver resection was as fast as 155 minutes. The same median operative time was reported for all patients by other centers,²⁹ however, the duration of the Pringle maneuver, which is most likely equivalent to the parenchymal phase of liver resection, was as long as 28 minutes with standard transection techniques.²⁹ The innovative advantage in using staplers is that the procedure is very fast in general, in contrast to CUSA. If this is confirmed in a randomized prospective clinical trial, this would present significant advantages for both the patient and the surgeon.

Belghiti *et al.* recently analyzed 747 hepatic resection.²⁷ In their patients the only independent predictor of operative death in patients with no underlying liver disease was concomitant extrahepatic procedures. Further, over time there was an increase of major liver resections

without an increase in morbidity and mortality. In contrast to their study, in our series only a small proportion (15%; 2/13) of patients died after combined liver and extrahepatic surgery, and most (77%; 10/13) of the deceased patients had undergone major stapler hepatectomy, where their findings are similar to those with conventional resection techniques (Table 5). Further, multivariate analysis revealed that elderly patients (≥ 70 years) and patients with a substantial intraoperative blood loss (≥ 1200 ml) had an increased risk for death within the postoperative phase after stapler hepatectomy. However, the patients' age had no impact on surgical morbidity; blood loss, however, clearly increased the risk of surgical complications (Table 6). Unlike a recent report that indicated that the overall improvement of perioperative outcome was mainly related to reduced mortality and morbidity in patients after major liver resection with blood transfusion as an important risk factor,³⁰ in our series with a large proportion of patients (63%) undergoing major liver resection, not only operative time but both blood loss and blood transfusion were identified as influencing surgical morbidity (Table 7). Janargin *et al.* observed that the improved perioperative outcome after liver resection in their patients was a result of a decreased number of liver segments resected.²⁹ While intraoperative blood loss per se and type of resection had an impact in the univariate analysis (Table 6) of our patients, this was not confirmed by multivariate analysis (Table 7). Major hepatectomy was the most time-consuming procedure, with a duration of >180 minutes in 79% of cases (Fig. 2a). Further, with a decrease in the operative time, a smaller number of patients with a blood loss of <1200 ml was observed, whereas the number of patients with a blood loss of ≥ 1200 ml increased significantly with an operative time of >180 minutes (Fig. 2c). Thus, both blood loss and type of resection have a strong correlation with operative time. The latter has been shown before to be important for early postoperative outcome.¹⁵ Further, we confirm that primary malignancy of the liver is a risk factor for surgical complications,^{15,38} which is independent of operative time in our series (Fig. 2b).

Clinical Implications

Our initial institutional experience with stapler hepatectomy is promising, and considering the data presented here, stapler hepatectomy may become a valuable, widespread, and safe technique for the parenchymal phase of liver resection with morbidity and mortality rates comparable to conventional resection techniques used by other high-volume centers.⁹⁻¹⁵ Because stapler

hepatectomy is both an effective and safe surgical procedure, controlled clinical trials are warranted to further investigate and develop this liver resection technique.

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Hepatic resection using stapling devices

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Abstract

Background: The progress and development of stapling devices has been remarkable. They have become indispensable for gastrointestinal diseases and are increasingly utilized in laparoscopic operations. Liver surgery applications for this technique are continuing to emerge, and in this study, we introduced the use of stapling devices to hepatic surgery.

Methods: We examined the operative procedure and efficacy of hepatic resections using stapling devices as follows: transection of Glisson's pedicle and the hepatic vein using endolineal stapling devices in right and left lobectomies; bisegmentectomy II and III en masse using a stapling device; and application of endolineal stapling devices to vessel transections and dissections of the hepatic parenchyma in laparoscopic hepatectomies.

Results: It was considered useful to tactfully apply stapling devices to vessel transections and dissections of the hepatic parenchyma in order to simplify the operative procedures of right or left lobectomies and lateral segmentectomies. Furthermore, the use of endoscopic stapling devices was an acceptable alternative to vessel transections and dissections of the hepatic parenchyma in laparoscopic hepatectomies.

Conclusions: We believe that stapling devices will become utilized in liver surgery hereafter. © 2004 Excerpta Medica, Inc. All rights reserved.

Keywords: Hepatic resection; Stapling device; Laparoscopic hepatectomy; Surgical technique

The progress and development of stapling devices has been remarkable, and they have become indispensable for gastrointestinal diseases. In addition, endoscopic stapling devices have become increasingly utilized in laparoscopic operations. However, stapling devices have been rarely used in operations involving the solid abdominal organs except for distal pancreatectomies. However, liver surgery applications for this technique are continuing to emerge [1–3]. In this study, we introduced the versatility and efficacy of stapling devices in hepatic surgery.

Operative techniques

Glisson's pedicle and hepatic vein transections using stapling devices in right and left hepatic lobectomies

For the transection of Glisson's pedicle (Fig. 1), the first branch of Glisson's pedicle was exposed after dissecting the

bifurcation of Glisson's sheath from the liver parenchyma following cholecystectomy. The right main portion of Glisson's pedicle for approximately 2 cm was exposed to allow safe stapling across Glisson's pedicle. In right lobectomies, Glisson's pedicle had to be dissected almost up to the anterior and posterior branches since the right main branch of Glisson's pedicle was often short. The left main branch of Glisson's pedicle was longer than the right and relatively easy to expose. Considering the thickness of Glisson's sheath, it was transected en masse by using an Endocutter ETS-Flex 35 or 45, blue type (Ethicon, Somerville, New Jersey) that fired three parallel rows of staples, 3.5 mm in height, which folded down to 1.5 mm after firing. These devices were blunt-ended, and were advanced slowly until placed across Glisson's pedicle. If it was difficult to insert the stapling devices, it became easier to precede transections of the hepatic parenchyma around Glisson's pedicle.

For transection of the hepatic vein (Fig. 2) according to the anterior approach, following the demarcation line clarified by the transection of the Glisson's pedicle, we exposed the inflow of the hepatic veins to the vena cava by transecting the hepatic parenchyma. The hepatic vein was dissected

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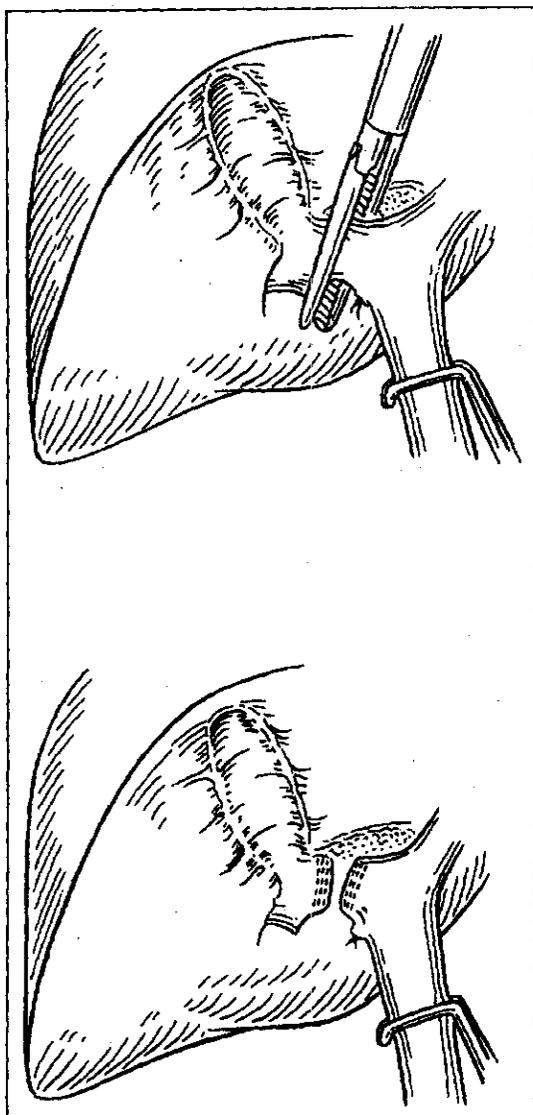


Fig. 1. Transection of the right Glisson's pedicle using an endolinesal stapler in right lobectomy.

with an Endocutter ETS-Flex 35, white type, which fired three parallel rows of staples (2.5 mm in height, and folded down to 1.0 mm). This technique could be easily applied even in conventional lobectomies that precede transections of the hepatic vein prior to transection of the hepatic parenchyma [3].

Bisegmentectomy II and III using stapling devices

To expose bisegment II and III completely, the falciform ligament, the left triangular ligament, and the left coronary ligaments were divided and the left hepatic vein was exposed. The linear stapler TL-90 was applied at bisegment II and III (Fig. 3) to form a maximum angle between the anvil

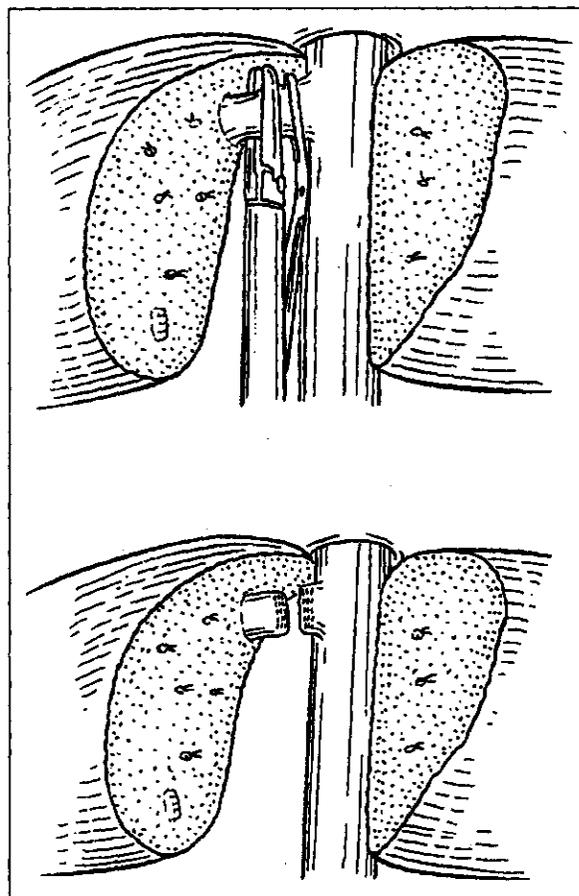


Fig. 2. Transection of the right hepatic vein using an endolinesal stapler in right lobectomy.

and the cartridge, with its ventral aspect at the left edge of the falciform ligament and its dorsal aspect at the left edge of the fossa ductus venosi. This positioning was used to hold the liver with enough margin from the tumor and subsequently compress the hepatic parenchyma gradually by screwing with the cartridge equipped with staples. When the gap setting was in a safe position and the staples were fired, the resected liver tissue was cut with a scalpel. As this device enabled only two rows of staples, however, it was necessary to reinforce the stump of the resection by running sutures.

Laparoscopic hepatectomy using stapling devices

We employed stapling devices for bisegmentectomy II and III especially in order to transect the S2 and S3 Glisson's pedicles, while the left hepatic vein was transected with Endocutter ETS-Flex 35 or 45. Recently, the stapling devices have been used not only for vessel transections but also for transactions of the liver parenchyma (Fig. 4). If such devices could be inserted, transections of Glisson's pedicles and the left hepatic vein could be achieved without

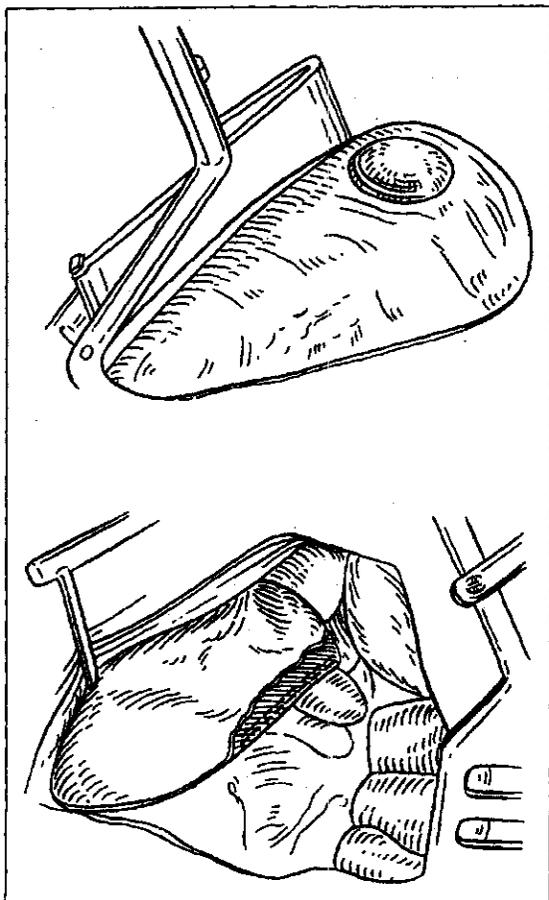


Fig. 3. Bisegmentectomy II and III en masse using a lineal stapler (TL-90).

its dissection in bisegmentectomy II and III. In addition, in cases of pedunculated hepatocellular carcinoma, immediate resection of the hepatic parenchyma has been possible with stapling devices [4].

Results

Transection of the main Glisson's pedicle and the hepatic veins with stapling devices during right and left hepatic lobectomies was applied in 15 cases; there were 8 cases of hepatocellular carcinoma and 7 cases of metastatic liver carcinoma. The mean operative time and the blood loss in the right lobectomy cases were, respectively 282 minutes (range 235 to 430) and 950 mL (range 390 to 3,620 mL); in left lobectomy cases, the corresponding values were 194 minutes (range 132 to 402) and 490 mL (range 280 to 2,000 mL). The percentages of patients with postoperative bleeding, bile leakage, and hospital death were, respectively, 6.7% (1 of 15), 13% (2 of 15), and 0% (0 of 15).

We used bisegmentectomy II and III with stapling devices in 15 cases including 6 cases of hepatocellular carcinoma,

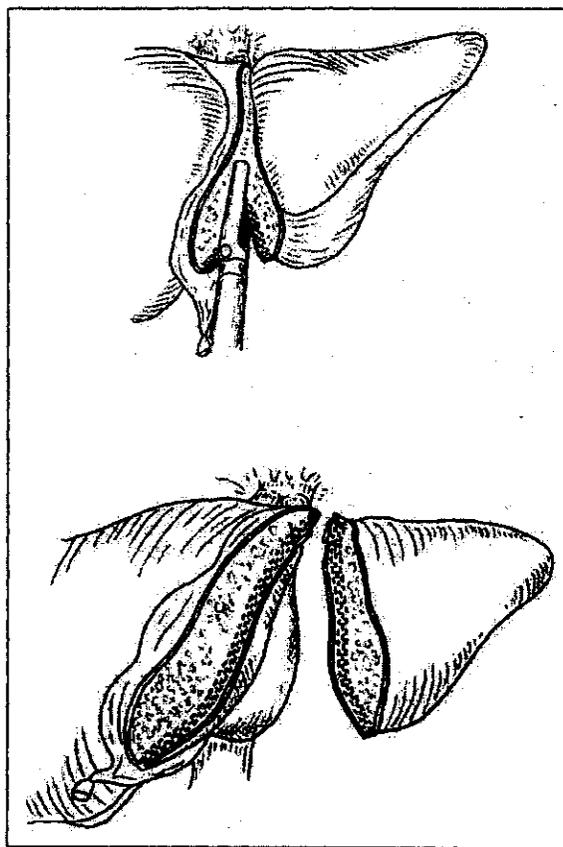


Fig. 4. Transection of the hepatic parenchyma using an endlineal stapler and a staple line in a laparoscopic bisegmentectomy II and III.

noma, 7 cases of synchronous metastatic liver carcinoma, and 2 cases of the liver trauma. Since all 7 cases involved either a simultaneously performed gastrectomy or colectomy along with hepatectomy, the mean operative time and blood loss only for the transection of bisegment II and III were measured. The mean operative time and blood loss were, respectively, 11 minutes (range 8 to 15) and 60 mL (range 20 to 120 mL). There was no postoperative bleeding, bile leakage, or hospital death.

Laparoscopic hepatectomy with stapling devices were performed in 34 cases: 10 cases (including 5 cases of hepatocellular carcinoma, 4 cases of metastatic liver carcinoma, and 1 case of hepatolithiasis) underwent laparoscopic bisegmentectomy II and III; 24 cases underwent laparoscopic partial hepatectomy. All 10 cases of laparoscopic bisegmentectomy II and III were performed with stapling devices. The mean operation time and the blood loss in the bisegmentectomy II and III cases were, respectively, 222 minutes (range 125 to 410) and 250 mL (range 120 to 610 mL). No patient experienced postoperative bleeding, biliary fistula, or hospital death. The patient's postoperative pain was minimal. With respect to resuming walking and eating, the postoperative clinical courses were uneventful. Neither port

site recurrences nor peritoneal disseminations related to the laparoscopic operation were observed during the long term.

The 3 cases of pedunculated hepatocellular carcinomas in 24 cases received partial hepatectomy with stapling devices. The operation time, blood loss, and duration of hospitalization were, respectively, 61 minutes, 35 mL, and 5.3 days on average, and their postoperative clinical courses were uneventful.

Comments

Glisson's pedicle is defined as the fibrous pedicle consisting of the portal triad within the hepatic parenchyma. The standard technique for performing a major hepatectomy is to separately divide the hepatic artery, portal vein, and hepatic duct. In patients with chronic hepatitis or cirrhosis, however, this technique often causes excessive blood loss and ascites accumulation because of preexisting coagulopathy and aggravation of portal hypertension. Thus, for right or left lobectomies it is useful and simple to control the main Glisson's pedicle totally en masse [5,6].

For transection of the main Glisson's pedicle in lobectomies, ligation or transfixing sutures are not sufficient due to its thickness, and continuous sutures are usually necessary. It is also generally necessary to use vascular clamps before transecting Glisson's pedicle. While a wide range of Glisson's pedicle is isolated to the extent required, vascular clamps sometimes slip out. MaEntree et al [1] and Voyles et al [2] first reported the use of stapling devices for transecting the portal vein and the hepatic vein. They used the TL type of linear staplers, which sutured one side with the insertion of vascular clamps in transecting vessels, requiring a certain length of vascular exposure. Yanaga et al [7] have been reported that TA or TL type linear staplers for transection of the right Glisson's pedicle and an endolinear stapler was applied for transection of the left Glisson's pedicle. The endolinear stapling device (Endocutter ETS-Flex 35 or 45) fires six parallel rows of titanium staples that immediately and safely transect with triple ligation of both proximal and distal sides.

It is safer and easier to use the endolinear stapling devices than other types of linear staplers to transect both the right and left main branches of Glisson's pedicles during hepatic lobectomies. It is unnecessary to insert vascular clamps or reinforce the resection stump by running sutures because it is possible to immediately suture and divide three rows on both sides with safety and certainty. So far, neither postoperative bleeding nor bile leakage has occurred, and this operative method is considered very useful. An important factor is the type of endolinear stapling device; the blue type should be used due to thickness of Glisson's pedicle, while the white type of endolinear stapling device is sufficient for transection of the hepatic vein. This method is applicable all type of liver tissue, even cirrhosis, if the patient tolerates the hepatic lobectomy. It is contraindicated,

however, when tumor thrombi are present in the main branch of portal vein or bile duct.

It is also easy to transect the hepatic veins with stapling devices. Recent cases have revealed that there was no problem in transecting the hepatic veins, without complete exposure in some situations, together with the hepatic parenchyma. This technique is a rapid and safe method for transecting the vessels, and it was unnecessary to use vascular clamps on the side of the vena cava.

Jurim et al [8] reported the operative procedure of bisegmentectomy II and III en masse using a stapling device (TL-90). Although they did not elaborate, it was effective for reduced size hepatectomy in liver transplant donors and bisegmentectomy II and III in cases with liver tumors. We, along with Jurin et al [8], reinforced the resected margin by continuous suturing. Whereas they transected the left hepatic vein in advance in some situations, however, we only exposed the left hepatic vein and transected the liver parenchyma altogether with stapling. We sometimes experienced difficult insertions of the bisegments II and III into the TL-90 when the liver exceeded about 4 cm in thickness, whereas we consider it possible to dissect the bisegments II and III of the normal liver with resiliency. A safe and immediate bisegmentectomy II and III took only about 10 minutes. What should be noted about this procedure concerns the need for reinforcement by suturing to maintain hemostasis given the risks of incomplete closure of bile ducts and occasional arterial bleeding with two rows of staplers by the TL type. To ensure adequate distance around the tumor, a 1 cm margin is required for safe stapler application.

Primarily, we considered this method very effective in cases with synchronous metastatic liver cancer lesions in otherwise normal livers, and in those who underwent liver trauma with difficulty in hemostasis. In the last three cases, this method was applied for resecting the relatively small and hard bisegments II and III of the liver with chronic hepatitis involving a hepatocellular carcinoma, resulting in shortening of the operation time and good clinical postoperative courses without complications. However, care must be taken as cirrhotic and enlarged liver would not be amenable to this technique.

A variety of laparoscopic instruments and devices such as an ultrasonic aspirator, a microwave tissue coagulator, and an ultrasonically activated device have been developed and have greatly contributed to establishing clinical applications of laparoscopic hepatectomies [4,10,11]. Furthermore, endoscopic stapling devices are also very useful for transection of the intrahepatic vessels and liver parenchyma especially in cases with bisegmentectomy II and III or the pedunculated tumor, as long as it is possible to insert the hepatic parenchyma planned for resection. The enlarged liver with cirrhosis would not be amenable to this technique, unless the staple could hold liver tissue or vessels.

We believe that laparoscopic hepatectomy has the benefits of shorter postoperative recovery time compared with

open hepatectomies [4,9,10], although this issue should be studied prospectively. It is likely that laparoscopic hepatectomy will not supplant open hepatectomy. However, the laparoscopic approach appears to be available surgical alternative in selected patients.

In the authors' experience, it is useful to employ stapling devices in dissecting the hepatic parenchyma and transecting vessels in order to simplify hepatic lobectomies and bisegmentectomy II and III. In addition, stapling devices could be applied to laparoscopic hepatectomies and could become one of the new and less invasive liver operations. Further study is required, however, to conclusively demonstrate these points. Although the critical factor determining the safety of liver surgery is the skill of the surgeon, stapling devices would partially supplant experience. We believe that stapling devices will be widely introduced in liver surgery hereafter.

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Laparoscopic Right Hepatectomy: Surgical Technique

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The objective of this study was to demonstrate the safety of laparoscopic right hepatectomy for benign or malignant disease. Many reports document the success of minor or segmental liver resections performed laparoscopically. Major hepatic resection has rarely been reported. This report documents our experience with 12 laparoscopic right hepatectomies. Ten patients had suspected malignancy, but all had lesions well clear of the midplane of the liver. The surgery followed three distinct phases: (1) Portal dissection during which diathermy and harmonic shears are used, clips are applied to the right hepatic duct and right hepatic artery, and a vascular stapler is used to divide the right portal vein; (2) dissection of the vena cava, which is usually done by tunneling below the liver using harmonic shears, clips, and a linear stapler to divide the right hepatic vein; and (3) parenchymal division during which harmonic shears and multiple firings of linear staplers are used to divide the liver substance. In five patients the procedure was completed totally laparoscopically, five patients had a laparoscopic-assisted procedure, and two patients had to be converted to formal open hepatectomy. Four patients required blood transfusion. There were no deaths and two cases of major morbidity—bile leakage in one and wound dehiscence in one. The average hospital stay was 8 days, but for those whose operations were completed totally laparoscopically, 4 days was the average. Two of the nine patients with documented cancer have since died—one with widespread intrahepatic hepatocellular carcinoma and another with widespread metastatic melanoma after resection of a colorectal metastasis. Seven patients with colorectal cancer are alive and disease free with follow-up of 6 to 24 months. Laparoscopic right hepatectomy is feasible in selected patients. It is technically demanding but can be safely accomplished by surgeons who have experience in advanced laparoscopic procedures and open hepatic surgery. (*J GASTROINTEST SURG* 2004;8:213–216) © 2004 The Society for Surgery of the Alimentary Tract

KEY WORDS: Laparoscopy, liver resection

The increase in sophistication of laparoscopic equipment has allowed the performance of many complex intra-abdominal operations. Laparoscopic hepatectomy can offer the usual advantages of minimal access surgery.¹ Most reported series of laparoscopic liver resections have documented nonanatomic or left lateral segmentectomies with only occasional major resections.^{2–5} Expertise at some centers has evolved to such an extent that even living related donor hepatectomy has been performed.⁶ Right hepatectomy, although first described by Huscher et al.⁷ in 1997, has not been widely reported.

This report documents our experience with the technique of laparoscopic right hepatectomy. The procedure is technically demanding but is possible in selected patients.

PATIENT SELECTION

From November 1999 to September 2002, one or the other of us attempted laparoscopic right hepatectomy in 12 patients. Eight patients were females who ranged in age from 41 to 75 years (mean 56 years). Nine patients had suspected colorectal metastases, two had focal nodular hyperplasia, and one had hepatocellular carcinoma in a noncirrhotic liver.

Case selection was based on patient and lesion characteristics. Slimmer female patients with minimal previous surgery were preferred. All lesions had to be well clear of the midplane of the liver to allow adequate surgical margins. All patients underwent CT assessment; MRI and PET scans were also available for some patients toward the end of the series.

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SURGICAL PROCEDURE

All procedures were performed under general anesthesia with the patient in the supine position and the surgeon standing on the patient's right looking at a monitor over the patient's right shoulder. Epidural anesthesia was used routinely to allow the anesthesiologist to maintain a low central venous pressure.

A pneumoperitoneum was established in all cases. Open access was performed and a pressure of 14 mm Hg was maintained. Five to six trocars were used with positioning dependent on body habitus and internal adhesions. A 12 mm port is needed in the right mid-clavicular line at the level of the umbilicus. This allows access of a linear stapler to divide the portal and right hepatic veins. The abdominal cavity and liver are assessed visually with a 30-degree laparoscope and with laparoscopic ultrasound. The procedure then follows three distinct phases: (1) portal dissection, (3) caval dissection, and (3) parenchymal division.

Portal Dissection. Cholangiography is performed via the cystic duct, but the gallbladder is not removed until later because it is useful in retraction. Using hook diathermy and harmonic shears (5 mm Ultracision; Ethicon, Cincinnati, OH), the right hepatic duct and artery are dissected and divided between clips. The right portal vein is carefully identified and divided with a linear stapler, and a line of

demarcation along the midplane of the liver is seen. Portal clamping is not routinely used, but a doubled sling can be placed around the portal triad for extra control in case of bleeding.

Vena Caval Dissection. The right hepatic vein is exposed from above using diathermy. It is difficult to divide from this angle, and the preferred extrahepatic approach is thus from below the liver. The liver is lifted anteriorly using two 5 mm graspers to create a tunnel, and the minor hepatic veins are divided with harmonic shears or clips. There is usually no need to mobilize the lateral peritoneal attachments. Working along the vena cava, the right hepatic vein will be seen against the diaphragm. The vein is divided from below with a linear stapler (Fig. 1).

Parenchymal Division. Following the line of demarcation along the midplane of the liver, harmonic shears and linear staplers are used to divide the liver. Up to nine vascular staplers have been used, insinuating the thin arm of the device through the liver substance, firing after resistance is reached. Bleeding can occur, most commonly from branches of the middle vein. This can be controlled by a repeat firing of the stapler, or suture ligation if the vessel is within the remaining liver. A low central venous pressure is helpful, as is the ability to suture quickly laparoscopically.

After liver transection, the lateral attachments of the right liver are divided and the specimen is removed using a plastic bag retrieval device through a

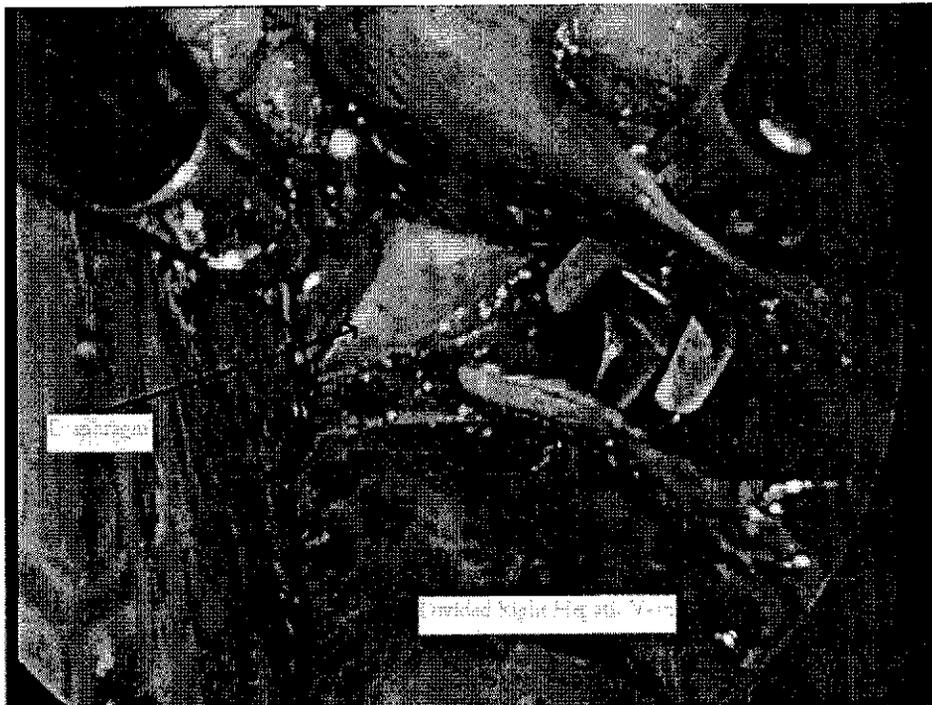


Fig. 1. Laparoscopic view of the right hepatic vein divided from beneath the liver.

wound of 5 to 6 cm, or the specimen is manipulated whole through an 8 to 10 cm wound with a plastic wound protector in place.

Hand ports were used in two cases, with placement in the right subcostal region. An assistant's hand was used to lift and retract the right lobe for parenchymal division and intrahepatic division of the right hepatic vein. This maneuver can be useful when complete caval dissection and right hepatic vein division cannot be accomplished by tunneling beneath the liver.

RESULTS

The operation was completed totally laparoscopically in five patients; in another five the operation was completed laparoscopically but assisted by a hand port or a 10 cm incision, which was needed to complete the hepatic transection; two patients were converted to an open hepatectomy. In one patient conversion was necessary because of unusual biliary anatomy; the other was the result of troublesome bleeding from minor hepatic veins. There was no catastrophic bleeding requiring rapid conversion. Four patients required blood transfusion of 1 to 4 units. Gas embolism was not seen or suspected in any of the patients. Operation times ranged from 5 to 7 hours.

None of the patients died, but major morbidity occurred in two patients. One case of bile leakage resolved spontaneously by day 8. One patient undergoing a laparoscopic-assisted procedure had wound dehiscence and right pleural effusion. The average length of hospital stay was 8 days for the whole group (range 2 to 21 days). For those undergoing a total laparoscopic procedure, the average stay was 4 days (range 2 to 7 days).

Nine patients had cancer. One had hepatocellular cancer and eight had solitary colorectal metastases. In one patient with suspected colorectal metastasis, no tumor was found on pathologic examination despite a positive PET scan. All lesions were well clear of surgical margins reflecting patient selection. The patient with hepatocellular carcinoma died at 12 months with multiple intrahepatic recurrences. One patient with colorectal cancer died of metastatic melanoma at 9 months. The remaining seven patients with colorectal cancer are alive and disease free with follow-up varying from 6 to 24 months. No port-site metastases have been seen.

DISCUSSION

We began performing laparoscopic wedge resections in the early 1990s and soon progressed to left

lateral segmentectomy. This is usually a very straightforward procedure in which, after the left lateral segment is mobilized, vascular staplers are used to divide the liver along the line of the falciform ligament.

Laparoscopic right hepatectomy is a much more technically demanding and time-consuming procedure. We have shown that in selected patients it can be performed with acceptable morbidity and low mortality. The most daunting step is parenchymal division with the potential problems of major bleeding and gas embolism. The risk of bleeding from the liver substance is reduced by maintaining low central venous pressure. Inflow and outflow control of the right lobe vessels obviously also reduces bleeding. We also used vascular staplers liberally. These staplers are expensive (up to \$1500 USD per case), but their effectiveness has led to increased usage in our open hepatectomy procedures, as has been reported by others.⁸

As others have shown, clinical gas embolism in laparoscopic hepatic surgery is surprisingly rare.^{9,10} The high solubility of carbon dioxide may explain this. The use of staplers to close veins quickly may also prevent large volumes of CO₂ from entering a low venous pressure system.

Clinical review of wound or port-site recurrence has demonstrated no specific oncologic disadvantage to laparoscopic procedures, per se, as long as standard principles are followed.¹¹ Indeed, a recent randomized trial of laparoscopic vs. open surgery for bowel cancer has demonstrated better oncologic outcomes in the laparoscopic group.¹² With laparoscopic right hepatectomy there may be an advantage in that the minor hepatic veins and right hepatic vein are divided from below the liver without the usual compression of the right lobe that occurs during a standard open right hepatectomy. Liu et al.¹³ have demonstrated fewer circulating tumor cells and a possible oncologic advantage when right lobe manipulation is minimized by an anterior approach at open surgery. Our technique uses even less hepatic manipulation prior to outflow division. We are currently conducting trials of routine laparoscopic caval dissection prior to open hepatectomy to minimize tumor compression.

CONCLUSION

Laparoscopic right hepatectomy is feasible and safe in highly selected patients with benign or malignant conditions. It can offer the usual benefits of laparoscopic surgery and may have an oncologic advantage. However, surgeons do need to have experience in

both advanced laparoscopic surgery and open liver surgery.

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A prospective evaluation of ultrasound-directed transparenchymal vascular control with linear cutting staplers in major hepatic resections

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Abstract

Background: We prospectively evaluated a novel ultrasound-directed technique of major hepatic resection using transparenchymal application of vascular staplers intending to minimize blood loss, operative time, and hepatic warm ischemia time.

Methods: Beginning in 1998 many major hepatic resections for hepatic tumors were performed with ultrasound-directed transparenchymal application of vascular linear cutting staplers. An endoscopic flexible neck vascular linear cutting stapler was used for control of the hepatic veins.

Results: From December 1998 to April 2003, 346 patients undergoing hepatic resection using this technique were identified from a prospective hepatobiliary tumor surgery database. Records were reviewed for blood loss, transfusion requirement, inflow occlusion (Pringle maneuver) time, overall operative time, and perioperative and postoperative complications. The average blood loss for all patients was 396 ± 28.4 mL. The inflow occlusion time was $13.7 \pm .64$ minutes with a total operative time of 140.7 ± 3.7 minutes. Additional liver-related procedures were performed in 52% of the patients. The overall complication rate was 29.5% with a 90-day mortality rate of 1.4%.

Conclusions: Ultrasound-directed transparenchymal application of vascular staplers to control inflow and outflow during major liver resection minimizes blood loss, warm ischemia time, and operative time compared to published reports of patients undergoing resection using other techniques. © 2005 Excerpta Medica Inc. All rights reserved.

Keywords: Liver resection; Ultrasound; Vascular staplers

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Stapler Hepatectomy is a Safe Dissection Technique: Analysis of 300 Patients

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Abstract

Background: In many surgical procedures, stapling devices have been introduced for safety and to reduce the overall operative time. Their use for transection of hepatic parenchyma is not well established. Thus, the feasibility of stapler hepatectomy and a risk analysis of surgical morbidity based on intraoperative data have been prospectively assessed on a routine clinical basis.

Materials and Methods: From October 1, 2001, to January 31, 2005, a total of 416 patients underwent liver resection in our department. During this period endo GIA vascular staplers were used for parenchymal transection in 300 cases of primary (22%) and metastatic (57%) liver cancer, benign diseases (adenoma, focal nodular hyperplasia [FNH], cysts) (14%), gallbladder carcinoma (2%), and other tumors (5%). There were 193 (64%) major resections (i.e., removal of three segments or more) and 107 minor hepatic resections. Additional extrahepatic resections were performed in 44 (15%) patients.

Results: Median values for operative time and intraoperative hemorrhage were 210 minutes and 700 ml, respectively. Further, transfusion of RBC and FFP was needed in 17% and 11% of patients, respectively. A postoperative ICU stay for >2 days was required in 18% of patients. The median postoperative hospital stay was 10 days (IQR 8–14 days). The most frequent surgical complications were bile leak (8%), wound infection (3%), and pneumothorax (2%). In 7% of cases after stapler hepatectomy a relaparotomy was necessary. Treated medical complications were pleural effusion (7%), renal insufficiency (5%), and cardiac insufficiency (3%). Risk assessment revealed that both operative time and indication for resection had significant impact on surgical morbidity. Mortality (4%) and morbidity (33%) were comparable to other high-volume centers performing conventional liver resection techniques.

Conclusion: In conclusion, stapler hepatectomy can be used in a routine clinical setting with a low incidence of surgical complications.

In the late seventies a multicenter analysis of hepatic resections for a variety of indications revealed that operative mortality was 13% and more than 20% for major resections, with 20% of the deaths resulting from intra-

operative bleeding.¹ With both occlusion of the hepatic inflow and total vascular occlusion, favorable results have been reported by Bismuth *et al.*² and Huguet *et al.*,³ followed by others.^{4–6} Because surgical technique is a major factor in preventing complications, various methods and instruments have been developed for safe, tissue-preserving dissection of the liver parenchyma.^{7,8} The

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introduction of the Cavitron Ultrasonic Surgical Aspirator (CUSA) and the Hydro-Jet Cutter has permitted large, non-anatomical wedge resections and liver resections to be performed with improved operative morbidity and mortality rates, typically about 30% and 5%, respectively, in high-volume centers.⁹⁻¹⁵

Today, staplers have become a vital instrument in a high number of surgical specialties. Vascular staplers have greatly facilitated the speed and safety of lobar resections of the lung.^{16,17} Since the nineties vascular staplers to divide hepatic veins¹⁸ and portal branches during hemihepatectomy are considered an achievement that aids in minimizing blood loss and thereby reduces the need for inflow occlusion.^{7,8,16-23} Further, staplers seem to be advantageous in the unroofing of hepatic cysts since any inadvertently injured bile duct or blood vessel is sealed.²¹ For the same reason, left lateral segmentectomies^{18,23} and wedge resections²⁴ have been performed with staplers as another nonselective dissection technique. Most recently, an ultrasound-directed transparenchymal application of vascular staplers to selectively divide major intrahepatic blood vessels before the parenchymal phase of liver resection has been shown to minimize blood loss, warm ischemia time, and operative time.²⁵ However, their use for dissection of liver parenchyma during liver resection is not well established, and the literature to date has included mainly anecdotal reports.^{23,24,26} The technique described here was introduced to our department after L. H. Blumgart, NY, USA had demonstrated this procedure to the senior author of this article.

Here we provide for the first time prospective acquired data on liver resection with endo GIA vascular staplers for complete transection of hepatic parenchyma and vasculature, a technique used in our routine clinical setting, with its associated surgical risk factors for the development of postoperative complications to index considerable feasibility and early postoperative outcome.

METHODS

A hepatobiliary patient database was established at the Department of General Surgery, University of Heidelberg, in October 2001. Since then, all patients undergoing liver resection for various hepatic tumors and other relevant indications were identified and analyzed prospectively. From October 1, 2001, to January 31, 2005, a total of 416 patients underwent liver resection. The surgical technique for transection of the parenchyma was dependent on the

preference of our 13 consultant surgeons; however, there was a strong inclination toward further developing the stapler hepatectomy. Thus, in 300 (72%) cases liver resection with endo GIA vascular staplers for hepatic dissection has been performed. Demographics, extent of resection, operative and transfusion data, complications, and hospital/ICU stay were documented prospectively. Further, a risk assessment of intraoperative parameters for postoperative morbidity after stapler hepatectomy has been performed. Therefore, the intraoperative parameters blood loss, operative time, type of liver resection, and extrahepatic resection were analyzed and adjusted for the confounding variables age, gender, and indication for liver resection.

Complications or death occurring either before hospital discharge or within 30 days after surgery were considered perioperative. Major complications defined as surgical or nonsurgical (medical) were defined and are listed in Table 1.

Surgical Technique

A single shot of mezlocilline (4 g) and metronidazole (0.5 g) was infused 30 minutes prior to surgery. Patients were placed in the supine position, prepared, and draped in a sterile fashion. The abdomen was initially explored for extrahepatic disease through a roof-top incision (with or without extension in the midline to the xiphoid), a reversed L-shaped incision from xiphoid to the tip of the twelfth right rib, or a standard transverse abdominal incision; no thoracotomies were necessary. After some initial mobilization of the falciform triangular ligament, dissection was carried out to expose the hepatic veins and the porta hepatis. Short hepatic and caudate veins from the inferior vena cava (IVC) were clipped or ligated to fully mobilize the liver. If hemihepatectomy or extended hemihepatectomy was performed, the appropriate hepatic arterial branch was divided between ligation with sutures, followed by division of the portal vein branch with the vascular stapler or via suture. The appropriate hepatic vein(s) was then divided with the endo GIA vascular stapler. After the transectional line was marked, the liver capsule was divided with diathermy. For subsequent dissection of the hepatic parenchyma, liver tissue was fractured stepwise with a vascular clamp (Fig. 1a) and subsequently divided with endo GIA vascular staplers (Fig. 1b). If necessary, intraoperative ultrasound was used to guide this dissection. After completed resection (Fig. 1c), the argon beam coagulation was applied to stop minor oozing. After hemostasis was secure, easy-flow drains were placed in

5/16/06

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To: The Record - It is my recommendation that the subject 510(k) Notification:

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- NOT substantially equivalent to marketed devices.
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(Division Director) (Date)

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		X
4. If, not, has POS been notified?		
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?	X	X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 061095

Reviewer: Sam Anzalone

Division/Branch: GRND/PRSS

Device Name: AUTO Entry Endo GBA Staplers

Product To Which Compared (510(K) Number If Known): K913802

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?		X	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If YES = Stop NE
5. Same Technological Characteristics?	X		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		X	If YES = Stop NE
9. Accepted Scientific Methods Exist?	X		If NO = Stop NE
10. Performance Data Available?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication: *The subject device has an extended IFU*
4. Explain why there is or is not a new effect or safety or effectiveness issue: *The extended indication includes liver tissue for which animal functional data provided.*
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough: *Because liver tissue is included some animal data are needed*
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: *Liver tissue indicates animal warrants some data (animal/clinical)*
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *Animal data and published clinical data demonstrate* 88

ATTACH ADDITIONAL SUPPORTING INFORMATION

**510(k) MEMORANDUM
K061095**

Date: May 4, 2006
From: Sam Arepalli, Ph.D.
To: File
Subject: K061095
Device: AUTO Suture Endo GIA Staplers
Classification: Implantable Staple, 21 CFR 878.4750, Class II
Product Code: GDW (Implantable Staple) & GAG (Surgical Stapler)
Common Name: Implantable Staple
Sponsor: United States Surgical, A Division of Tyco HealthCare
150 Glover Avenue
Norwalk, CT06856
Contact: Frank Ginelli
203 492 5352

S. Plude 5/26

Recommendation:

The subject device is recommended found substantially equivalent to predicate devices

REVIEW

1. INTENDED USE

Subject Device:

The Auto Suture ENDO GIA Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction and creation of anastomoses. **It may be used for transaction and resection of liver substance, hepatic vascular and biliary structures.**

Predicate Device:

The Auto Suture ENDO GIA Staplers (K0913802, K913832 & K900129) have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction of tissues.

Discussion of Equivalency:

The subject device has an extended indication for use, i.e., “It may be used for transaction and resection of liver substance, hepatic vascular and biliary structures” compared to the predicate devices which were cleared previously under K0913802 & K900129.

2. COMPARISON OF TECHNICAL CHARACTERISTICS (DESIGN, MATERIALS, SIZES ETC.) WITH PREDICATE DEVICE:

The subject device is identical to the predicate device that was cleared under K900129. The subject device is an articulating, disposable, linear stapler that simultaneously transects and staples various types of internal tissues. It fires two sets of three staggered rows of titanium staples and simultaneously divides the tissue between the two sets of rows. Each set of the rows will begin and end with two staples. It can be used in both endoscopic and open surgical procedures. It is available in multiple sizes and for endoscopic procedures it can be introduced and used through appropriately sized trocar endoscopic access cannulae.

The device consists of an instrument, an elongated shaft, a single use loading cartridge containing the staples and the cutting blade, and an anvil on which to form the staples. The cartridge and anvil portion may be articulated through various angles to provide increased access and versatility. It also locks into a rigid coaxial orientation with the shaft to allow passage through a trocar with relative ease. There are three rigid positions of articulation including the 0° (entry position), 22° and 45° (maximum articulation).

The instrument has a trigger that is manually squeezed once to close the anvil to clamp the tissue. Once the anvil is fully closed, it securely retains the tissue until it is opened. To fire the instrument, a safety must be physically and intentionally disengaged after full clamp-up. Once the safety has been disengaged, the trigger can be squeezed additional times to fire the staples and advance the cutting blade. The number of firing squeezes will increase with cartridge length. The cartridge assembly has graphics to indicate distance fired and cut line.

At any time after clamp up, the anvil may be opened by fully retracting the mutual retraction knobs. If the instrument's safety has been disengaged, and a firing stroke initiated, the process of retraction will disengage a lock-out preventing the cartridge from being re-fired to prevent injury. Proper loading of the SULU (single use loading units) is required to allow firing. Improper loading will prevent firing. The SULU will not be able to be disengaged and removed unless the device is in the unclamped state.

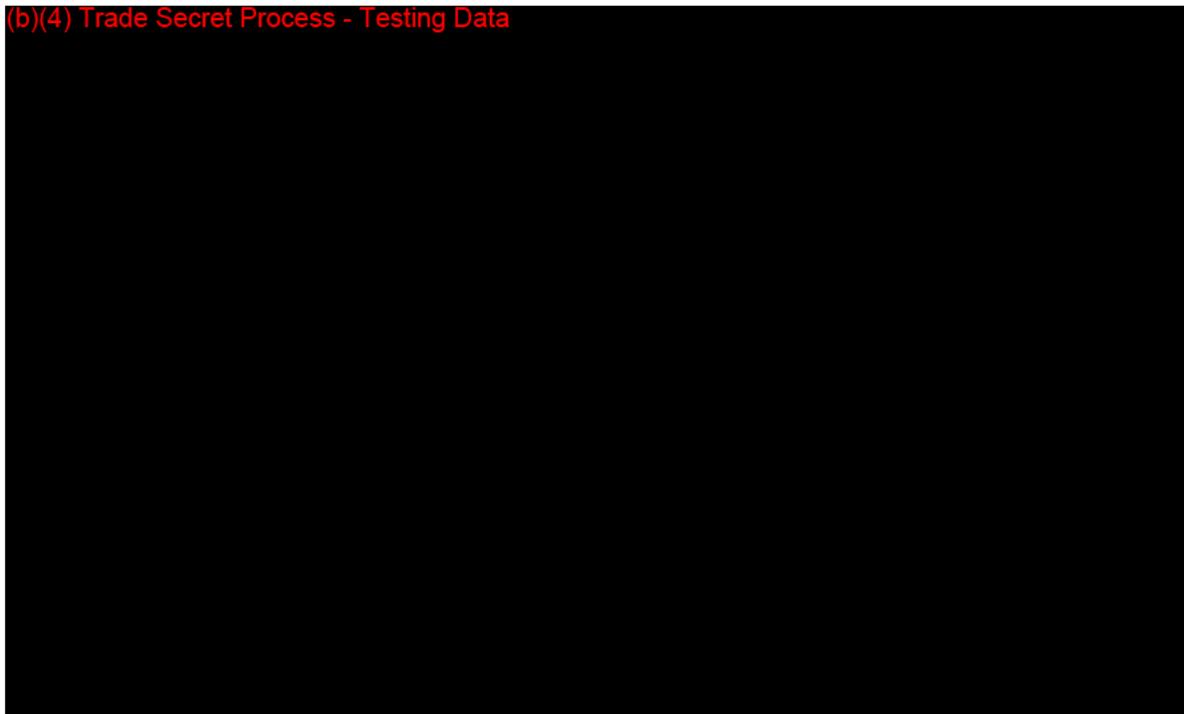
3. COMPARATIVE DATA

The sponsor provided performance data in animals and literature describing the device studies in humans.

Animal Data:

The subject device was tested for its efficacy on canine liver tissue (Evaluation of Liver Tissue in Canine).

(b)(4) Trade Secret Process - Testing Data



Clinical Data:

The sponsor provided clinical literature articles describing the subject device on human liver tissue. This information is reviewed by Herb Lerner, MD and found to be satisfactory (see his attached note).

Risk Assessment:

None

4. DOES THE PRODUCT CONTAIN DRUGS OR BIOLOGICALS?

No, the subject device does not contain any drugs. It is not combination product.

5. STERILIZATION

The subject device is sterilized by EtO and is validated by AAMI/ANSI/ISO 11135:1994 method for an SAL of 10^{-6} .

Pyrogenicity Claims:

None

Packaging:

The device s are packaged in a PVC blister to which is sealed a coated TYVEK cover.

Shelf-life/Expiry Date:

The packaging is identical to the predicate device and therefore, the shelf-life remains 5 years.

6. LABELING

The package insert provided contains the following: device description, indications for use, contraindications, warnings and precautions, and instructions for use.

7. CLAIMS

None

8. ADMINISTRATIVE INFORMATION

- Truthful and Accurate Statement: See page 23
- 510(k) Summary/Statement: See page 22
- Indications for Use: See page 20

9. SUMMARY

The subject device is identical to that of the predicate device. There is no change in the design or materials (see Device Description section of this memo). The sponsor likes the subject device cleared for the extended indication, “It may be used for transaction and resection of liver substance, hepatic vascular and bilary structures”. In support of the extended indication, the sponsor provided functional data in animals (canine liver) and literature articles describing the use of subject device on human liver tissue for resection and transaction. The literature information provided is reviewed by Dr. Herb Lerner and found to be acceptable. There has been no change in sterilization, packaging and other aspects of the device.

Therefore, the subject device is recommended found substantially equivalent to predicate device.

10. CONTACT RECORD

The sponsor was contacted on 5/4/06 and Mr. Frank Ginelli was requested to identify the predicate device that included the indications “anastomosis of tissues”.

Mr. Ginelli stated that the same device that was cleared under K913802 contained the anastomosis of tissues indication.



Sam Arepalli, Ph.D.
FDA/CDRH/ODE/DGRND/PRSB



Date

Clinical Consult
K061095

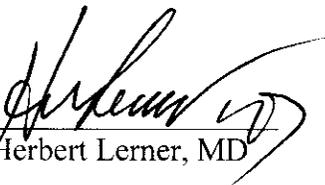
To: The Record
From: Herbert Lerner, MD
Date: May 4, 2006
Subject: Auto Suture Staplers
Sponsor: US Surgical
Contact: Frank Gianelli

History: I have been asked to review this traditional 510 (k) for the expanded indication of these well known surgical staplers for **resection of liver substance, hepatic vasculature and biliary structures**".

These capabilities of these staplers to achieve hemostasis and complete closure of hollow structures (blood vessels, lymphatic channels and bronchi), used during open and laparoscopic surgical procedures, are well documented. The sponsor now wishes to add the above bolded procedures, based on a small animal study and literature review. I have used these staplers for many years, including during surgical procedures included in these new indications.

The literature provided by the sponsor is from highly respected, peer reviewed journals. The small animal study documents well that the staples will do as expected in this new environment.

Recommendation: I fell that the sponsor has provided adequate material to support SE recommendation.


Herbert Lerner, MD

MEMO TO THE RECORD
510(k) REVIEW
K913802 & K913832

DATE: October 3, 1991
FROM: BIOLOGIST

OFFICE: HFZ-410
DIVISION: DSRD/SDB

COMPANY NAME: United States Surgical Corporation (USSC)
DEVICE NAME: Auto Suture^R Powered Endoscopic GIATM Stapler - K913802
Auto Suture^R Powered Endoscopic TA^R Stapler

1. Critical Devices ? YES
2. Implants (short-term or long-term)? Yes, Long-Term
3. Software-driven? N/A
4. Device(s) to which equivalence is claimed and manufacturer:
The sponsor is claiming SE to the Endoscopic Linear GIA Staplers (K892233 and K900129) as well as the Powered LDS Disposable Stapler (K900043) for the GIATM Stapling device and SE to the Endoscopic Linear TA^R (K910192) as well as the above referenced powered stapling devices for the TA Stapling device. Also substantially equivalent to the PSSTM and the PFSTM powered skin and fascial staplers also marketed by USSC.
5. Submission provides comparative specifications: YES
comparative in vitro data: NO
summary of animal testing: N/A
summary of clinical testing: N/A
6. Description of device and its differences from pre-enactment/predicate device(s). (b)(4) Trade
(b)(4) Trade (b)(4) Secret Process
(b)(4) Trade Secret Process - Product Specs

[Handwritten signature]

(b)(4) Trade Secret Process - Product Specs

7. **Recommendation:** Based on my review of the information contained in these submissions, I recommend a finding of substantial equivalence for these devices.

8. **Classification:** 79, Class II GDW, Implantable Staple


Frances Moreland Curtis, M.S.B.
Plastic and Reconstructive Surgery Devices Branch
Division of General and Restorative Devices

7

15

MEMO TO THE RECORD
510(k) REVIEW
K900129

*Predicate Device
fwk061095*

DATE: 2/21/90
FROM: BIOLOGIST

OFFICE: HFZ-410
DIVISION: DSRD/SDB

COMPANY NAME: United States Surgical Corporation
DEVICE NAME: Modified Auto Suture Endoscopic GIA Surgical Stapler

1. Life-supporting or life-sustaining? yes
2. Implant (short-term or long-term)? yes, permanent
3. Software-driven? N/A
4. Device(s) to which equivalence is claimed and manufacturer:
K892233, same as above, only not modified.
5. Submission provides comparative specifications: yes
comparative in vitro data: N/A
summary of animal testing: N/A
summary of clinical testing: N/A
6. Description of device and its differences from pre-enactment/predicate device(s), [REDACTED] (b)(4) Trade Secret Process (b)



7. Recommendation: Based on the information contained in this submission, I recommend a finding of substantial equivalence for this device.

8. Classification: Class II
Product Code GDW

21 CFR 878.4750, Implantable Staple

Frances M. Moreland

Frances M. Moreland
Plastic and Reconstructive Surgery Devices Section
Division of Surgical and Rehabilitative Devices

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4.

Auto Suture®
DISPOSABLE ENDOSCOPIC GIA™
Surgical Stapling Instrument*

K900129

Indications:

The Auto Suture® DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler* has application in endoscopic, gynecologic, and general abdominal procedures for the transection and resection of tissues.

Effects:

The DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler* places two triple staggered rows of stainless steel staples, and simultaneously divides the tissue between the two triple rows. The size of the staple is determined by the selection of the V or 3.5 stapler.

Schematic View and Nomenclature

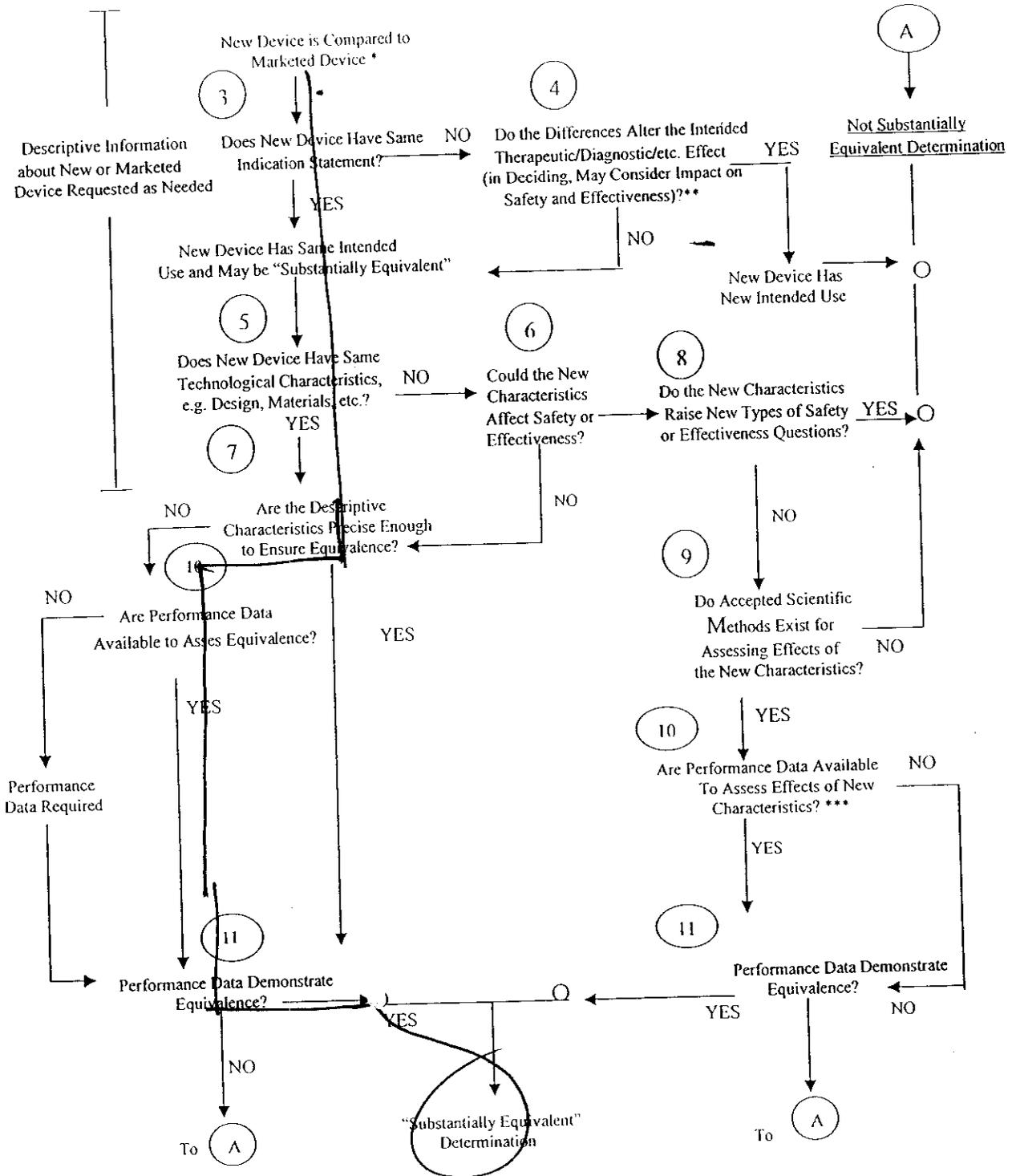
Auto Suture® DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler*

(Artwork)

*Trademark name not yet determined.

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510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- * 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.