

c



Field Quality Engineering Report

Evaluation of Reprocessed Ethicon Endo-Surgery Single Patient Use (SPU) Devices

October 1999

EXECUTIVE SUMMARY

A total of 37 reprocessed EES single patient use (SPU) devices were acquired for purposes of conducting engineering analyses and observing the effects of reprocessing and reuse. All devices were received unopened in the reprocessor packaging. The engineering analyses are divided into four stages as listed in **TABLE 1**. Packaging was evaluated in **Stage 1**. The physical condition of these devices is assessed in **Stages 2,3, and 4**.

TABLE 1 TESTING ACTIVITY AS OF OCTOBER 10, 1999

Stage	Analysis	Devices Tested
1	Visual inspection of device and package	37
2	Visual inspection of device after removal from package	12
3	Functional testing to manufacturing quality standards	12
4	Internal inspection (device disassembled)	10

All devices analyzed through **Stage 1** exhibited packaging or labeling non-conformances to EES quality standards. Instructions for use, indications, precautions, warnings and contraindications were not provided with any of the 37 devices inspected. Of the reprocessor packaging analyzed, 17 (46%) occurrences of physical damage were observed. These occurrences included tears, punctures or damaged seals. These defects compromise the sterile barrier and contradict the reprocessor's assurance of product sterility.

Of the 12 devices analyzed through **Stages 2 and 3**, five (41%) were physically damaged or missing components. Under microscopic examination, six of the 12 devices exhibited biological debris, greasy or gummy residues or particulate matter (as described in the referenced RDL reports).

An AL326 (5 mm clip applier) failed to function as required. This device contained only 13 of the required 20 clips, and misfired five times during the test. Force-to-fire on one ER320 (endoscopic clip applier) was higher than normal. This device also exhibited abnormal, audible and tactile feedback when fired.

The results from this testing indicate that the practice of reprocessing SPU devices degrades product quality. The absence of adequate labeling increases the risk of improper use. Testing will continue for the remaining reprocessed devices on hand. Additional testing will be performed as reprocessed product continues to be received from the field.

1.0 Introduction

In April 1998, an engineering analysis was conducted on 11 different Ethicon Endo-Surgery disposable devices. The reported findings included the observation of tissue debris, dried blood and body fluid on all 11 products. Electromechanical instruments failed functional testing, and numerous examples of packaging non-conformances and damaged product were also reported. Based on their condition, none of these devices would have met EES quality acceptance criteria for product release.

In May 1999, a conference co-hosted by AAMI and the FDA on the *Reuse of Single-Use Devices* took place in Washington, DC. Additional information regarding the risks associated with reprocessing was presented and discussed. Based on the concern for these risks, a request for additional reprocessed devices was issued to specific EES U.S. field sales representatives. These devices were acquired for a second investigative study that was launched in July of 1999.

2.0 Purpose

The primary purpose of this engineering study was to investigate the effects of reprocessing on EES single patient use (SPU) devices and examine possible degradation in device quality. The evaluation of these devices focused on packaging, product condition and functionality. Of particular concern was that the EES SPU devices in this study were never designed for multi-patient use or to be cleaned effectively for the purpose of reuse.

3.0 Materials

Reprocessed EES devices involved in this study were acquired in strict compliance with all applicable guidelines. Although a wide variety of products (e.g. mechanical, endoscopic, electrosurgery, etc.) was targeted for analysis, the actual receipt of product was random, based on what was available in the field. A total of 37 instruments was received from the field, representing 22 different product codes. Please see **TABLE 3** for a complete list of products.

All but one of these devices were reprocessed by three commercial firms: Alliance Medical, Orris and Vanguard Medical Concepts (**TABLE 2**).

New EES products (same product codes) were tested in parallel with the reprocessed devices to provide the required control in conformance with applicable test methodology.

TABLE 2 DISTRIBUTION BY REPROCESSOR

	Alliance Medical	Orris	Vanguard Medical Concepts	Hospital
Devices	24	2	10	1

TABLE 3 LIST OF INSTRUMENTS RECEIVED

Tracking Number	Type of Instrument	Code	
R0001	Modified Allis Clamp, 10 mm	MBA10	
R0002	Modified Allis Clamp, 10 mm	MBA10	
R0003	Curved Scissors with unipolar cautery	DCS12	+
R0004	Curved Scissors with unipolar cautery	DCS12	+
R0005	Curved Dissector with unipolar cautery	DCD32	-
R0006	Curved Scissors with unipolar cautery	DCD32	+
R0007	ALI PORT 5mm Multiple Clip Applier	AI 326	-
R0008	ALI PORT 5mm Multiple Clip Applier	AI 326	-
R0009	Stability Sleeve, 10/11 mm, 100 mm	512ST	-
R0010	Stability Sleeve, 10/11 mm, 100 mm	512ST	-
R0011	Multiple Clip Applier with rotating shaft, M/I	FR320	-
R0012	Multiple Clip Applier with rotating shaft, M/I	FR320	-
R0013	Reloadable Linear Stapler, heavy wire, 90mm	TLH90	-
R0014	Endoscopic Rotating Clip Appliers	FR320	-
R0015	Endoscopic Rotating Clip Appliers	FR320	-
R0016	TROCAR sleeve, 12 mm	512SD	.
R0017	TROCAR with dilating tip, 5mm	3551D	-
R0018	TROCAR with dilating tip, 12mm	511SD	-
R0019	TROCAR with stability thread, 12 mm	512B	-
R0020	Pneumo needle for insufflation	PN120	-
R0021	Graspers for unipolar cautery (green)	DSG23	
R0022	Graspers for unipolar cautery (green)	DSG23	
R0023	Graspers for unipolar cautery (green)	DSG23	
R0024	Graspers for unipolar cautery (green)	DSG23	
R0025	Curved intraluminal stapler	CDH21	
R0026	Laparoscopic coagulating shears, 15mm	LC515	+
R0027	Laparoscopic coagulating shears, 15mm	LC515	+
R0028	Laparoscopic coagulating shears, 15mm	LC515	+
R0029	Laparoscopic coagulating blade, 15mm	CS150	
R0030	Laparoscopic coagulating blade, 15mm	CS150	
R0031	Linear cutter, 55mm	TL C55	-
R0032	Reloadable Linear stapler, heavy wire, 90mm	TLH90	-
R0033	Reloadable Linear stapler, vascular	TLV30	-
R0034	Trocar with dilating tip	355SD	-
R0035	Endopath Trocar, 33mm	TLK33	-
R0036	Endopath Trocar, 18 mm	TL C18	-
R0037	Endopath Trocar, 18 mm	TL C18	-

4.0 Methods and Scope

In planning this study, the first step was to develop and implement a strategy to acquire reprocessed EES disposable devices from the field. This strategy was communicated to appropriate field sales management. A documentation and tracking system was established in which each reprocessed device is catalogued along with source information, observations, and specific findings.

A detailed engineering study protocol was developed to provide product-specific and sequential testing format. Functional testing follows the same test methodology and associated quality requirements currently used in manufacturing as criteria for product release. The Reliability and Development Lab (RDL) system is used to coordinate the testing and store test data. RDL reports are received and retained in hardcopy. Photographic documentation is stored in the same PC directory (digital format) as are the tracking sheets received from sales representatives.

Per the engineering test protocol, the scope of this testing is defined in four stages (refer to **Table 1**). Staging the sequence assures that all testing is as thorough as possible and that one test will not impact or influence the outcome of the next test.

Due to concern for possible contamination and in conformance to company policy, opened products are handled as if they were field returns. Biological hazard safety precautions are followed. Visual inspection includes the use of high magnification where indicated. The RDL microscopist performs chemical testing for blood when its presence is suspected. Digital photos are taken of critical details.

5.0 References

FQET-005. Engineering Study for Testing Reprocessed Single Patient Use (SPU) Products EES Process and Material Specifications (listed in FQET-004 and/or the RDL Test Reports RDL Test Reports: TR numbers: 9315, 9316, 9317, 9323, and 9331
Evaluation of Reprocessed Ethicon Endo-Surgery Single-Patient-Use Medical Devices, Ethicon Endo-Surgery, Inc., April 1998

6.0 Definitions

RDL - EES Reliability and Development Lab

Process Specifications - manufacturing and in-process test procedures for a product.

Material Specifications - performance criteria a manufactured product must meet when tested in process.

End-Effector - the patient contact (proximal) end of the device. Examples of these are blades, scissors, graspers and hooks for electrosurgical or Ultracision applications.

Tenting - occurs when a pointed object, upon impact or applied force, has physically strained and weakened a material at the point of contact.

7.0 Observations and Conclusions

Packaging Quality

Of the 37 reprocessed devices analyzed through **Stage 1**, 17 (46%) exhibited punctures, seal damage and tears in the packaging. In four packages, the device was unrestrained (to move within the package) and no protective tip was provided, as is required for new EES product. These devices migrated into and damaged the seal margin. *Even when devices were double-bagged, damage occurred that created openings in both the plastic film and Tyvek layers.* In one instance (CS150 Ultracision coagulating blade), a puncture extended through the package from front to back.



PHOTO 1. Tear Through Two Layers of Packaging



PHOTO 2 Package Torn at Trocar Cannula Edge

Reprocessor packaging consisted of a Tyvek-backed pouch (or double-pouch). In contrast, EES ships all products in thoroughly tested and validated packaging. EES packaging is designed to immobilize and cushion the device, protecting it from potential damage incurred during shipping and handling. Measures are also taken to protect the package from sharp corners or points on a device.

New EES clip applicators, UltraCision end-effectors and electrosurgery devices are shipped with protective tips. The tips are intended to protect both the package and the end-effectors from damage during shipping and handling. The operation of the UltraCision generator is critically dependent on the surface condition of the end-effectors: if a nick or scratch is present on the end-effector, the generator will emit a constant audible tone and will not function. Investigating customer complaints of this nature have traced the constant audible tone and generator failure to this cause. Thirteen of the reprocessed devices did not have tip protection when packaged. For four other devices, tips were present but loose inside the reprocessor's packaging. ✓

Tenting occurred near end-effectors, knobs, thumb wheels and other angular or prominent features on the devices. Tenting occurs when a pointed object, upon impact or applied force, has physically strained a material at the point of contact. The packaging material is weakened at that point and is susceptible to tearing upon subsequent contact and/or pressure.

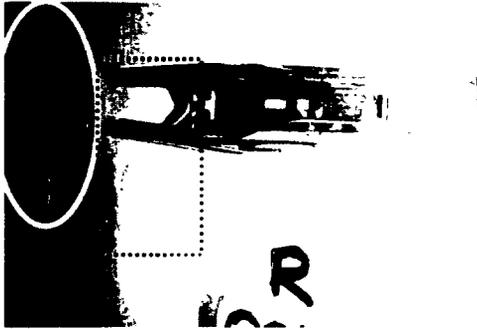


PHOTO 3. Margin Damage (oval) and Tenting (rectangle)

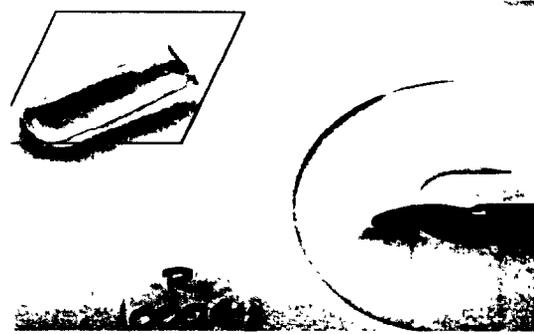


PHOTO 4. Loose Tip Protector in Package

Product Condition

Three handheld laparoscopic electro-surgical devices had bent shafts. In one case, a curved scissors with cautery was bent approximately 35° off the shaft axis. Though these devices may still function, a bent shaft will impede insertion and removal of the device through a trocar. This has been verified through the investigation of customer complaints related to difficult insertion/removal (for the same product codes). In this situation, these devices have been known to incur additional damage upon insertion or removal. Two specific failure modes have been identified through complaint analysis: (1) unintended removal of the end-effectors, and (2) nicking the protective sheath. Damage to the protective sheath (insulator) has been known to correlate with burns at or near the targeted site for electro-surgery.

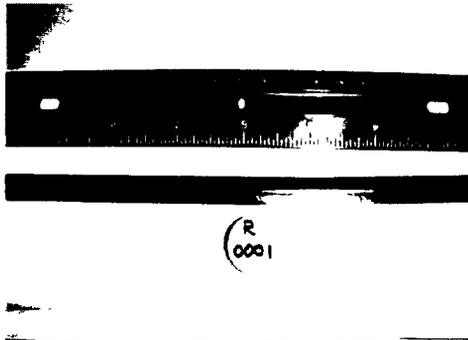


PHOTO 5 Bowed Shaft of MBA10

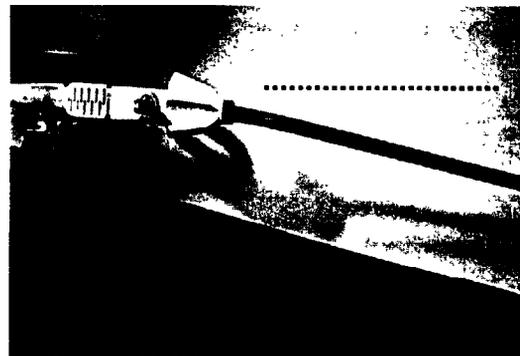


PHOTO 6. Bowed Shaft of DCD32.(Dotted Line is Straight)

On one electro-surgical curved scissors (DCS12), the protective sheath had receded. This results in a larger area of potential contact to the patient that can result in unintended burns.



PHOTO 7. New and Used DCS12's

Physical damage was observed in two locations on one trocar: a complex crack near the stopcock and a chipped leading edge (insertion surface).

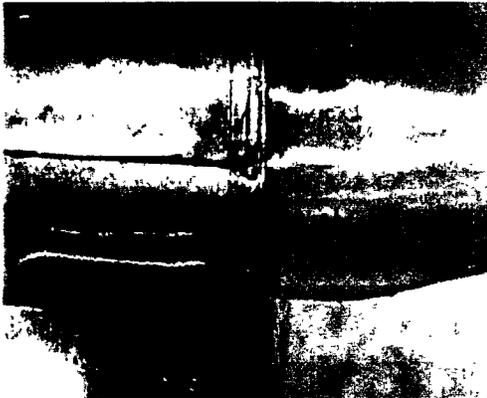


PHOTO 8. Crack in Trocar Near Stopcock



PHOTO 9. Chip in Leading Edge of Trocar

Advanced corrosion was seen on the jaws of one ER320 clip applier. Mechanical wear, nicks and scratches were observed on four handheld devices.



PHOTO 10. Corrosion on Jaw of ER320 Clip Applier

Upon visual inspection of the 12 devices observed under high magnification, six (50%) exhibited clear evidence of biological debris and/or contamination. A fingerprint on one trocar was determined by chemical reagents to be dried blood. These observations were made prior to disassembling the device for additional inspection



PHOTO 11. Trocar Cannula With Blood That Appears To Be A Smearing Fingerprint.

While firing an AL326, a one-eighth inch mass of blood and proteinaceous material was ejected with the clip. The clip itself contained additional blood and tissue. Similar material was found at the base of the clip applicator jaws and in the clip track.



PHOTO 12. Mass of Blood and Tissue Ejected by AL326



PHOTO 13. Second Clip Deployed by AL326. [Note contamination oozing from clip.]



PHOTO 14. Contamination in Lower Jaw of AL326

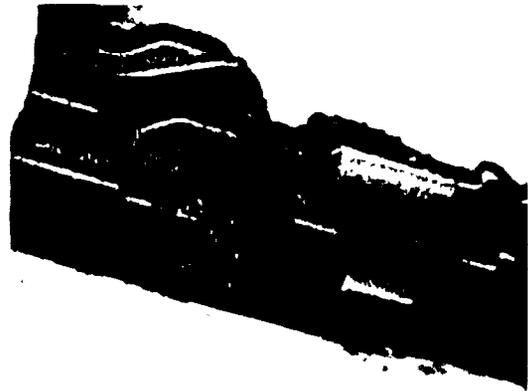


PHOTO 15. Another Section of the Lower Jaw of the AL326

Three performance issues were found on one AL326 clip applicator.

- 1) The device contained 13 clips: EES product labeling requires 20 clips.
- 2) The device misfired five times between the 12th and 13th clip.
- 3) Under microscopic examination, another clip was found to have jammed in the device. When investigated, the jamming was attributed to a build up of tissue/blood debris in the clip feed track.

PHOTO 16. AL326 Clip That Would Not Deploy



A total of four reprocessed ER320's (endoscopic clip applicators) were tested. Force-to-fire on one was higher than normal. This device also exhibited abnormal, audible and tactile feedback when fired.

8.0 Summary

Based on analyses to date of reprocessed EES SPU devices, none would have met EES quality standards and release criteria. These nonconformances to EES release criteria are summarized in **TABLE 4**.

TABLE 4 SUMMARY OF ISSUES

Type of Nonconformance	Number of Nonconformances	
Labeling	all 37	(100%)
Packaging	15 [#] of 37	(46%)
Device Condition	6 of 12	(50%)
Foreign matter/contamination	6 of 12	(50%)

* On two packages, more than one defect was observed

Reprocessor inspection and testing do not appear capable of assessing the condition or functionality of these devices compared to original EES product quality. Attempts to clean these devices from prior use have not been effective. Packaging was found to be substandard (within the medical device industry) in terms of product protection, sterility assurance and proper labeling. It is therefore concluded that the reuse of these devices poses a significant risk to patients and health care providers.

Pgs. 10-12 were not included in Att. C

**Field Quality Engineering Report,
Evaluation of Reprocessed Ethicon Endo-Surgery Single Patient Use Devices
Ethicon Endo-Surgery, Inc.**

Date: October, 1999 (submitted with this abstract)

Objective: To investigate the effects of reprocessing on single patient use devices and examine possible degradation in device quality.

Methods: A total of 37 samples of reprocessed single patient use devices were obtained for study. The sample population was obtained randomly from hospital shelves and included clip applicators, clamps, sleeves, cautery devices, needles, staplers, coagulating shears, trocars and cutters. All samples were assessed for package integrity, product integrity and product performance criteria.

Results: Observed Failures:

Packaging (n=37):	17/37 (46%)
Product Quality (n=12):	6/12 (50%)
Foreign Material/Contam. (n=12):	6/12 (50%)

Multiple failures were observed and attributed directly to reprocessing. These included tears and/or breaks in the device packaging, off-axis bends and kinks in linear instruments, damaged protective sheaths in electrocautery devices, cracked/chipped trocars and corroded clip applicators (blood/proteinaceous matter). In addition, performance failures were observed with several clip applicators and linear staplers.

Conclusions: Based on device design and materials, reprocessing single use devices of this type cannot be performed reliably and/or in a safe and efficacious manner. Such reprocessing jeopardizes patient safety as well as the safety of health care providers who use them.