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Laparoscopic Trocar Injuries: A report from a U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) Systematic Technology Assessment of Medical Products (STAMP) Committee: FDA Safety Communication

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Abstract

Background : Laparoscopic trocars, which are associated with reports of death and life-threatening injury, are used in increasing numbers for an increasing range of procedures. We evaluated trocar injuries and provide recommendations for prevention. Methods: We reviewed the published literature, FDA's product recalls data, trocar labeling, and patient educational brochures. Results: Patient injuries appear to occur most frequently during initial trocar insertion. Increased morbidity and mortality result when laparoscopists or patients do not recognize injuries early or do not address them in a timely manner. Conclusions: To reduce morbidity and

mortality associated with trocar injuries requires diligence on the part of manufacturers, health care practitioners, regulators, and patients to recognize, manage, and mitigate the risks. Improved trocar labeling and design, laparoscopist training, patient education, and reporting of adverse events should also assist.

This paper reports on FDA review activities related to laparoscopic trocar injuries. FDA observed an increase in the number of trocar injury reports received during 1999 and 2000. This prompted FDA to convene a Systematic Technology Assessment of Medical Product (STAMP) committee to study the issue. The committee members included FDA staff with expertise in health care, engineering, and human factors. The committee completed the following activities:

- Analysis of FDA adverse event surveillance data
- Review of the published literature
- Review of FDA product recalls data
- Analysis of trocar labeling
- Analysis of patient brochures on laparoscopic surgery

The results of the analysis of FDA adverse event surveillance data is reported separately. The results of the other activities are included in this report.

Background

In order to perform a laparoscopic procedure, typically from two to four or five trocars, or access ports, are inserted into the abdominal cavity to allow entry of the required laparoscopic instruments. Insertion of these trocars carries a risk for life-threatening injury. Between 1997 and mid-2002, FDA received more than 1300 laparoscopic trocar-associated injury reports, including reports of approximately 30 deaths.

The number and breadth of laparoscopic procedures has increased steadily since the late 1980s. Each year, more than 2 million patients undergo laparoscopic procedures in the U.S. (see Table 1). Estimates of the numbers of trocars used in the U.S. indicate a steady increase from just over 3 million in 1994 to nearly 4.8 million in 2000, and a projected 6.2 million in 2004 (1).

Literature Review

We reviewed the relevant published literature on injuries related to the use of laparoscopic trocars, including peer-reviewed journals, technical reports, and market data. We gained the following insights from the published literature.

Scope of the problem:

Hemorrhage due to vessel injury and infection secondary to bowel injury, especially when diagnosis is delayed, are the most serious complications and the most likely to result in death. Most data suggest that the rate of trocar related complications is less than 3% (2-9). However, the Wherry review (10) of patient records in military facilities found a 6% complication rate. The average incidence of trocar-related vascular injuries is approximately 0.1%. Bowel injuries are reported to occur more frequently, with the average incidence less than 1%. Mortality rates are typically reported at 0.1% or less.

Reasons for trocar injuries :

Injuries appear to occur most frequently during insertion of trocars into the abdomen or pelvis. Several studies (2, 6, 9, 11, 12) suggest that the initial trocar insertion is the most dangerous aspect of trocar use, and possibly the most dangerous step in minimally invasive surgery. A 1996 study (6) found that 83% of vascular injuries, 75% of bowel injuries, and 50% of local hemorrhage injuries were caused during primary trocar insertion.

Corson (11, 13) noted that major vessel injuries are almost invariably operator error and that delayed recognition of injury in patients older than 59 was significantly associated with fatal outcome (14). Examples of vascular lacerations are presented in Figure 1. A 1996 study (6) indicated that operator experience had the greatest effect on rate of vascular injuries and a lesser effect on visceral injuries.

Laparoscopist Technique :

Minimally invasive surgery typically involves use of multiple trocars and cannulas. The first trocar inserted, or primary trocar, is used to place a cannula through which a laparoscope is inserted to view internal structures. Other, secondary, trocars provide for insertion of other instruments such as biopsy forceps, etc. The primary trocar is typically inserted using either a “blind” puncture or a Hasson (“cut-down,” or open) method (15).

Before inserting the primary trocar some general surgeons and most gynecologists introduce carbon dioxide gas into the abdominal cavity (creating pneumoperitoneum) through a Veress needle - a process called insufflation. Insufflation elevates and holds the abdominal wall away from internal structures. In 1998 ECRI (16) estimated that 40% of surgeons used Veress needle insufflation prior to primary trocar insertion, while 30% used a direct (no insufflation) trocar insertion method, and 30% used the Hasson method. The literature does not indicate a difference in complication rates for direct entry versus a preliminary pneumoperitomeum.

The blind insertion of the primary trocar uses a technique referred to as a “controlled jab.” The force required can vary from patient to patient and from trocar to trocar depending upon the sharpness of the trocar blade. The laparoscopist must apply sufficient force under adequate control to stop the trocar movement upon penetration. The amount of force required may correlate with the risk of injury. Injuries may occur twice as often when associated with difficult trocar insertion (9). Corson et al (17) reported that the force required to insert reusable trocars was twice that for disposable trocars. This is due to the fact manufacturers use different alloys (that are compatible with autoclaving) for reusable trocars than for disposable trocars. The alloys used for reusable trocars are difficult to sharpen and do not allow for as sharp cutting edges as are found on the disposable trocars. Hence the force necessary for insertion is greater for reusable trocars.

Although it may seem intuitive that the Hasson technique (using an open approach) for trocar placement is safer than blind trocar insertion, the level of safety provided is the subject of some debate (3, 10, 11, 18). Corson (11) opined that the Hasson technique offers little protection from bowel injury but reduces major vessel injury. A 1995 study (18), involving 360 laparoscopic procedures, associated an open approach with 2 of the 6 bowel injuries that occurred.

Along with the Hasson procedure, several other -- sometimes conflicting -- techniques have been set forth in an effort to improve the safety of primary trocar insertion. Semm (19) advocated blind access with a Veress needle and insufflation before primary trocar insertion. Injuries related to the blind Veress needle insertion led to studies on alternative methods. Some suggest it is safer to skip the Veress needle step altogether and use a direct trocar insertion technique (20-23). Some (24) recommended open dissection and identification of the tissue layers during Veress needle placement. Others (25) recommended high pressure insufflation during the primary trocar insertion in order to create more space between the abdominal wall and internal structures. Hulka (26) suggested laparoscopists can minimize the risk of major vessel injury by having an assistant stand at the head or foot of the operating table and confirm the correct insertion angle.

Hurd et al (27) showed through tomography that the location of the aortic bifurcation relative to the umbilicus varies with the patient weight, with the umbilicus located more cephalad in heavier patients and caudally in thinner patients. Corson (14) recommended against use of the umbilicus as an anatomic landmark and instead recommended (for all but the most obese patients) palpation of the aorta to its bifurcation and insertion of a Veress needle below that point by tunneling horizontally from the infraumbilical fold until the actual point of entry below the aortic bifurcation as a “Z” technique.

Many advocate elevating the abdominal wall before blind insertion of the primary trocar or Veress needle placement to reduce the risk of injury of internal structures (see Figure 2). In patients with a history of prior abdominal surgery, internal structures may adhere to the abdominal wall and be elevated into the trocar’s path. Some advocate the use of microlaparoscopy to reduce injuries when adhesions are anticipated (28). Corson recommends, for patients with previous lower abdominal surgery, entry in the left upper quadrant, a location referred to as Palmer’s Point that is typically void of internal structures.

Hurd et al (29) recommended transillumination to visualize the location of blood vessels in the abdominal wall so that they can be avoided during trocar insertion.

Anecdotal data suggest some laparoscopists believe they can detect by tactile sense when a trocar penetrates the abdominal cavity. However, one study (30) found that in the majority of insertions, the trocar cutting tip entered the abdominal cavity before the laparoscopist recognized that penetration had occurred.

Trocar design :

Early trocars were simple devices used for paracentesis (see basic design features in Figure 3). More complex designs were developed as laparoscopic surgery was introduced. Trocar tips are designed for either sharp or blunt penetration (see Figure 4). Today, trocar designs include a myriad of device designs including more than 100 brands from than more than 20 manufacturers (based upon review of FDA Medical Device Registration and Listing Database).

In 1984, a trocar was introduced with a retractable shield that covers the tip before and after insertion. The purpose of the shield is to protect abdominal and pelvic organs from inadvertent puncture. Whether shielded trocars offer protection against injuries is the subject of debate. A 1996 study (6) of 103,852 operations involving the use of 386,784 trocars found that ten out of the 26 (39%) serious injuries and two out of the seven (29%) deaths involved shielded trocars. In a 1995 retrospective study of 3,591 laparoscopic procedures, Saville & Woods (7) found four major retroperitoneal vessel injuries all of which involved shielded trocars. In 2000, ECRI (31) reported that the laparoscopists it consulted disagreed about the benefit of shielded trocars. Laparoscopists' attitudes about shielded trocars appear to be influenced by the laparoscopists' training and experience with the various trocar designs. ECRI's report concluded that when used properly, shielded trocars may provide a margin of safety, but that the shield may create a false sense of security and lead to undue reliance upon it.

In 1996, based upon a lack of data to support safety claims, FDA asked manufacturers to refrain from using the term "safety trocar" to refer to shielded trocars (32). Our 2002 review of trocar labeling and promotional materials located no "safety" claims for shielded trocars.

A trocar use survey of 63 healthcare facilities (33) indicated that shielded trocars were used for primary trocar insertions by 37% of surgeons exclusively, by 59% for at least 90% of procedures, and by 79% for at least 50% of procedures.

Optical-access trocars were introduced in 1994 as an alternative to the blind insertion. These allow laparoscopists to view the cutting tip as it penetrates the tissues. Studies (30, 36, 37) suggest optical-access trocars may provide some protection over blind insertion. Even with use of optical trocars, some injuries are reported in the literature (11, 37).

The Ternamian device (35), a special type of reusable trocarless cannula system, allows optical visualization during the process. The Ternamian device works on the principle of an Archimedes screw, lifting the abdominal wall with no downward vector. Many knowledgeable laparoscopists believe the Ternamian device could greatly reduce vascular injury, but it has not been aggressively marketed and has not gained a large market share.

Radially-expanding trocars that have blunt tips and use smaller abdominal incisions may provide some protection from injuries. Clinical evaluations (38, 39), prospective randomized clinical studies (40-42), a review of malpractice claims (11), as well as earlier animal studies (43) suggest these devices may reduce the incidence of injuries.

Data limited:

We found that reliable data on trocar injury rates are elusive; locating both numerator data and denominator data is problematic. We found that the most frequently cited studies are retrospective, including reviews of patient records and device user surveys. Additionally, neither published data nor FDA adverse event surveillance data are adequate to associate trocar injuries with specific device types or brands. Data from surveys (9) and government studies (44, 45) suggest that injuries are under-reported. FDA adverse event surveillance data reveal that adverse event reports frequently lack the device model and brand name and that the involved device is seldom evaluated for defects or malfunction.

Product Recalls Data Review

We reviewed the FDA recall data from 1997 through 2001 for information on device design problems. Our review located four trocar recalls; however, only one recall involved device integrity or device function that could result in a traumatic injury. This recall occurred in 1997 and involved broken cannulas. The other recalls involved other issues such as sterilization problems and the use of the wrong label.

FDA frequently receives reports of broken trocars and trocar components, sometimes associated with patient lacerations and device fragments left in patients. The committee considered whether manufacturer standards might address these issues. We were unable to locate any current manufacturer standards for trocars. We located only one standard dated 1961 (46).

Product Labeling Review

We requested trocar labeling (on-package labels and package inserts) from firms listed as active in the FDA Medical Device Registration and Listing Database under the laparoscope product code. We received and reviewed labeling for more than a hundred different trocar brands and models from more than twenty manufacturers. We analyzed the labeling for selected elements and validated any phone numbers included in the labeling. Also, we reviewed the package inserts and analyzed for the inclusion of selected elements (see Table 2). We found that none of the labeling included all selected elements and that the labeling was not consistent in content or format. We noted the following areas be considered for labeling enhancement:

- Unclear instructions for use
- Use of exceedingly small print, especially in package inserts
- Inadequate or poorly labeled illustrations
- Absence of a clearly defined statement of intended use
- Absence of information on materials of construction

In addition to labeling, several manufacturers submitted advertising and promotional materials. In some cases the advertising and promotional materials provided more information than the device labeling.

Patient Brochures Review

We gathered and reviewed laparoscopic surgery brochures from the Society of American Gastrointestinal Endoscopic Surgeons, the American College of Obstetricians and Gynecologists, and the American College of Surgeons. We analyzed the content and format of the brochures for accuracy, clarity, and completeness as recommended in an FDA guidance document (47).

We found these materials provided some excellent information and that they used the appropriate reading level for the layperson. We found the following deviations from FDA's recommended content and format:

- Not all medical terms were defined (either parenthetically in the text or in a glossary)
- Insufficient numbers of or inadequately labeled illustrations for surgical procedures and anatomical structures
- Some brochures were not dated to indicate whether information was current

Discussion

Trocar use requires considerable training, practice, skill, manual dexterity, adequate muscular strength, knowledge of the associated risks, and careful patient selection. Debate continues over the protection provided by fail-safe features in preventing trocar related injury (shields, optics, radially-expanding designs). Due to their unique design and use issues, trocars with these features may require additional training, knowledge, or skill.

Data are lacking to fully assess the scope of the problem and the effectiveness of proposed solutions. The diverse opinions and lack of consensus on methods to address these issues highlight this. The complexities of executing well-controlled clinical trials are well known. Data from other less burdensome sources such as FDA adverse event surveillance do not provide a complete picture. Many device injuries are never reported to FDA (44, 45). Often the involved device is discarded or not returned to the manufacturer to determine whether a malfunction contributed to the injury. Anecdotal data suggest that health care professionals are unfamiliar with the need to report device-related problems to FDA. This lack of knowledge may contribute to the under-reporting and to the high frequency with which trocars involved in injuries are discarded without an evaluation.

Laparoscopists may be inclined to blame themselves when a patient is injured during a procedure. However, in addition to laparoscopist-related issues (trocar insertion technique, patient selection, injury recognition and effective intervention), the lack of standard device designs, a lack of proven-effective fail-safe features, and failure of patients to report symptoms in a timely manner may also contribute to morbidity and mortality.

Manufacturer advertising and promotional materials may provide better trocar use information than does trocar labeling. It is important that all users have access to high quality trocar use information. Manufacturers should provide clear, complete, and accurate trocar use information with each product sold, including information on the inherent risks associated with trocar use.

Recommendations

To prevent deaths and injuries associated with laparoscopic trocars, we recommend:

- Laparoscopists:
  - Completely familiarize themselves with a new device or new device design before first-time use. To do so, they should study the device use, indications, contraindications, warnings, cautions, and precautions. Laparoscopists may find information in manufacturers' written materials, videotapes and CDs, discussions with and hands-on demonstrations by device manufacturer representatives, and discussions with and observation of colleagues using the device.
  - Perform procedures proctored by an experienced laparoscopist, until they are comfortable with their skills, before attempting the procedure unassisted
  - Select patients properly, using laparoscopic surgery for those patients at low risk for complications. Laparoscopists should consider alternatives to blind trocar insertion (laparotomy, Hasson method, radially-expanding and optical-access designs) for:
    - Patients with a history of prior abdominal surgery -- entry in the left upper quadrant (Palmer's Point) should be a first-line option to eliminate major vessel injury and entry injuries into the bowel which might adhere to a previously made lower abdominal incision.
    - Children
    - Small thin adults
    - Patients with lower abdomen skin that cannot be adequately stabilized for safe insertion of the Verres needle or trocar to achieve pneumoperitoneum (women after multiple pregnancies, patients with atrophic abdominal musculature, thin patients)
  - Before beginning a procedure, assure that adequate injury intervention support facilities and personnel are available
  - Be vigilant in observing for injuries and immediately upon recognition of injury apply appropriate surgical management
  - Apply ergonomic principles to position themselves and their patients during surgery, in order to maximize control over their movements and reduce fatigue
  - Use effective risk communication. Laparoscopists should inform patients of the risks associated with the use of trocars, possible complications, and the signs and symptoms of injury that patients should be alert to.
  - Report adverse events involving the use of trocars per institutional protocol or through FDA's voluntary adverse event reporting program, MedWatch at **https://www.accessdata.fda.gov/scripts/medwatch/ (https://www.accessdata.fda.gov/scripts/medwatch/)**or 1-800-FDA-1088.
- Trocar manufacturers and device regulators:
  - Apply human factors engineering principles into trocar designs
  - Enhance product labeling by incorporating human factors engineering principles as outlined in FDA's labeling guidance (47)
  - Incorporate the following ideal elements into on-package labels:
    - Content and format clear and easy-to-read
    - Manufacturer name and address
    - Device name and clear reference to component information in the package insert
    - Valid telephone number
    - Listing of all package contents
    - Re-use instructions or statement that device is for single use
    - Sterility status of contents
    - Statement referring reader to the package insert instructions-for-use (if not included in on-package label)
- Standards-setting organizations:
  - Develop manufacturer standards that incorporate human factors engineering principles into trocar designs
- Professional organizations,

- Develop technical information for trocar users on device selection, patient selection, use techniques, injury intervention
- Provide effective patient education materials that incorporate human factors to aid laparoscopists with pre- and post-operative patient instruction

- Laparoscopic surgery patients:
  - Be familiar with the risks of any recommended laparoscopic surgery
  - Ask their laparoscopists about alternative procedures
  - Carefully read all pre-operative and post-operative materials
  - Clarify any unclear or confusing instructions
  - Make sure they understand the signs of an unrecognized trocar injury
  - Seek medical attention immediately if signs develop

Table 1. Number and type of laparoscopic procedures performed annually in the U.S.*

Type of Procedure	Total Procedures	Number (%) performed laparoscopically
General Surgery Procedures:		
Cholecystectomy	1,084,882	922,150 (85)
Adhesiolysis	215,760	155,347 (72)
Hernia repair	820,191	114,827 (14)
Appendectomies	334,388	73,565 (22)
Nissen fundoplication	47,087	44,733 (95)
Colon resection	380,000	26,600 (7)
Gynecology Procedures:		
Adnexa removal	350,059	227,538 (65)
Sterilization	684,000	342,000 (50)
Hysterectomies	582,000	87,300 (15)
Myomectomy	64,977	45,484 (70)
Urology Procedures		
Pelvic floor reconstruction	160,000	64,000 (40)
Total	**4,723,344**	**2,103,544**

* Sterilization numbers based on 1994-6 data from Centers for Disease Control and Prevention, and include approximately half performed postpartum and half interval procedures not related by timing to a pregnancy (48). All other numbers based on 1999 data (1)

Table 2 Trocar manufacturer labeling elements and percent that included each element*

Labeling Element	% of labeling that included
Manufacturer name	100
Manufacturer address	90
Valid manufacturer phone number	75
Manufacturer contact information clear and easily accessible	50
Specific device name	90
Device identification number	20
Intended Use statement	70
Instructions for Use	70
Useful device illustration(s)	15
Contraindications for use	60
Use of signal words (“Precaution,” “Warning”)	70
Sterility status of the device	85
Device materials of construction	30
Device reuse instructions	60

*Based on review of labeling from > 100 models and brands from > 20 manufacturers.

Figure 1. Examples of vascular lacerations caused by: (a) a pyramidal trocar tip; (b) a tip shield; (c) a Veress needle striking from directly above (upper left) and at an angle (lower right)

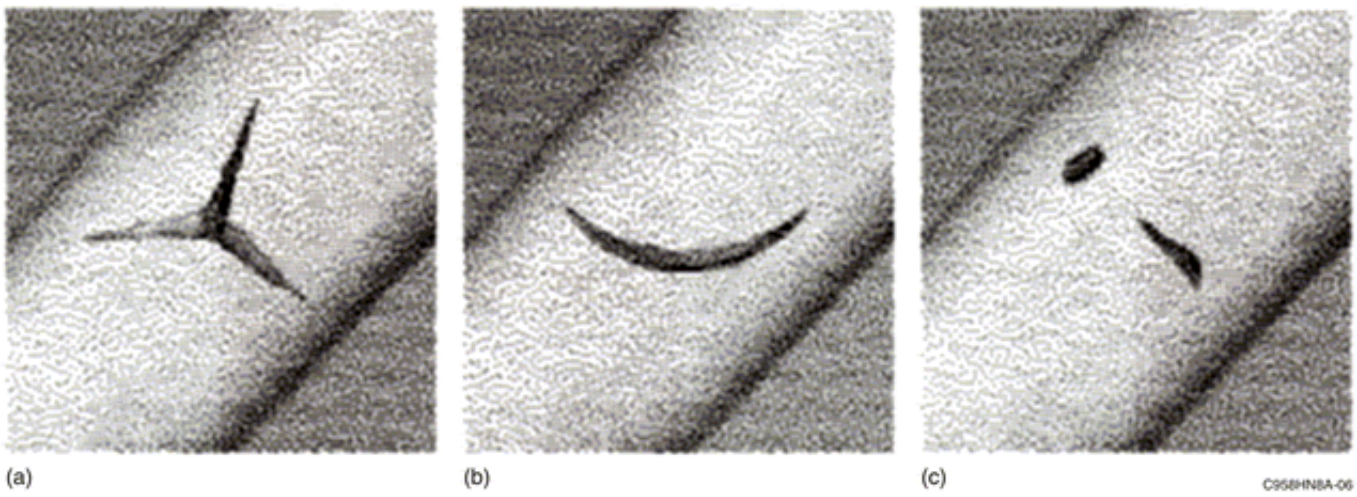


Figure 2. Elevation of the abdominal wall during trocar insertion

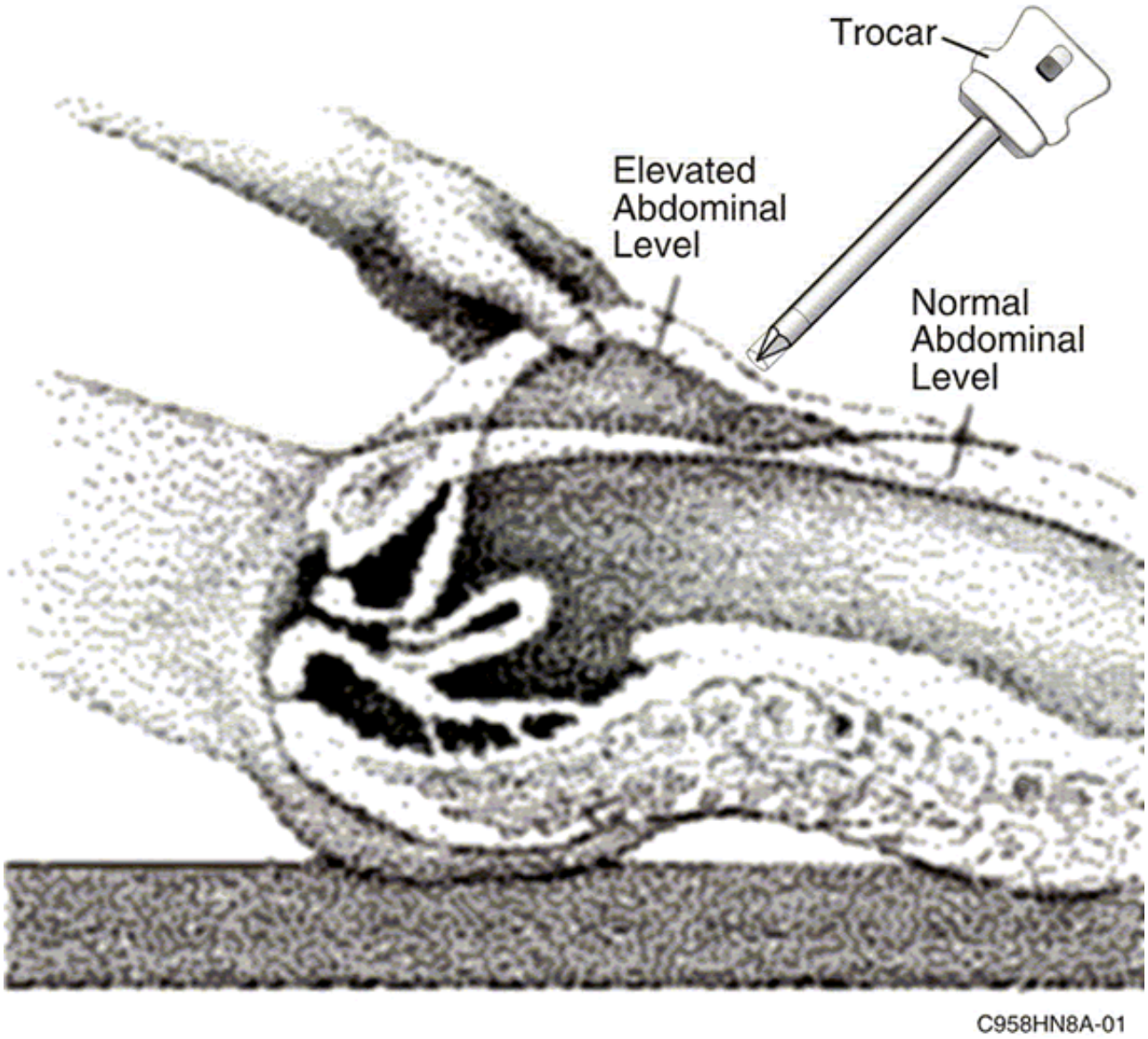


Figure 3. Trocar/cannulae system

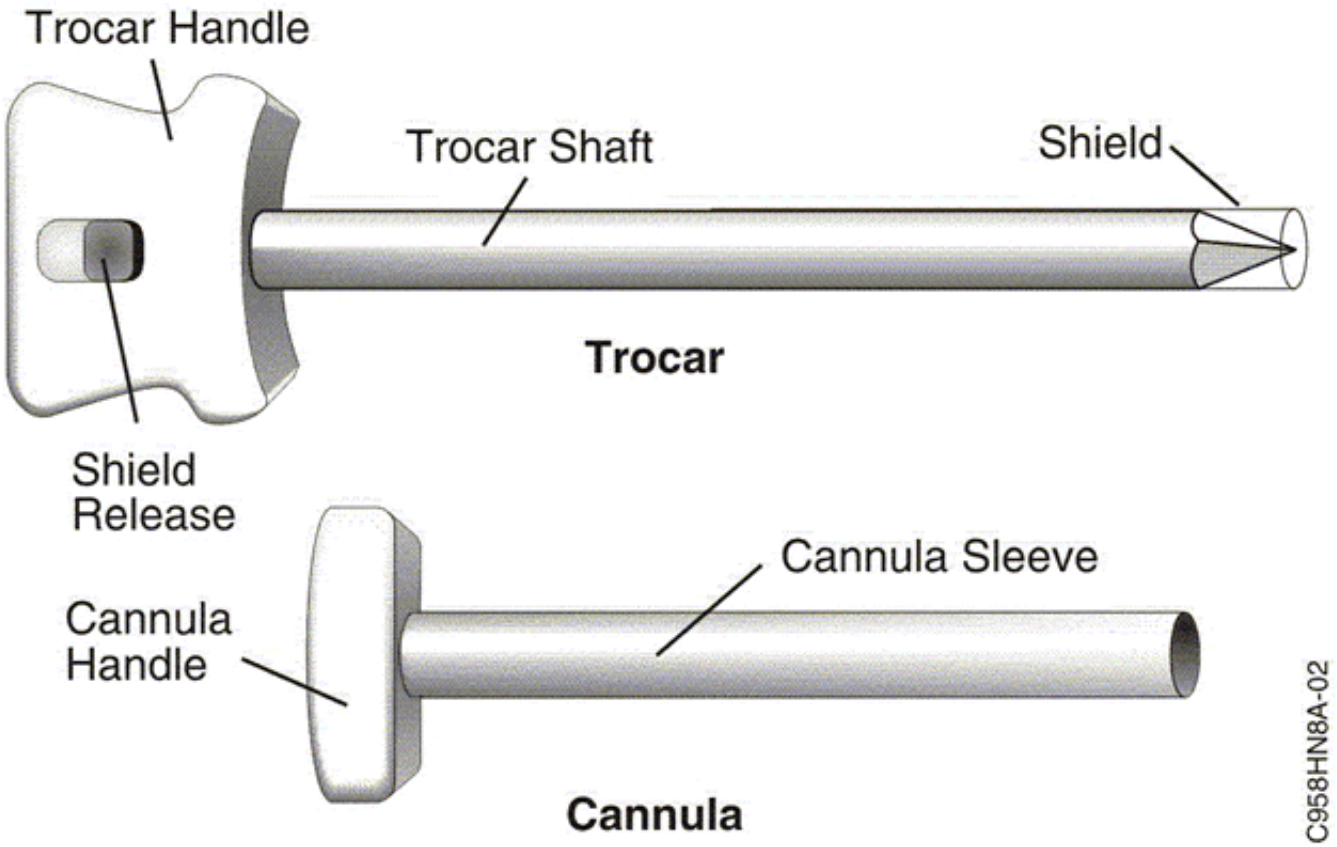
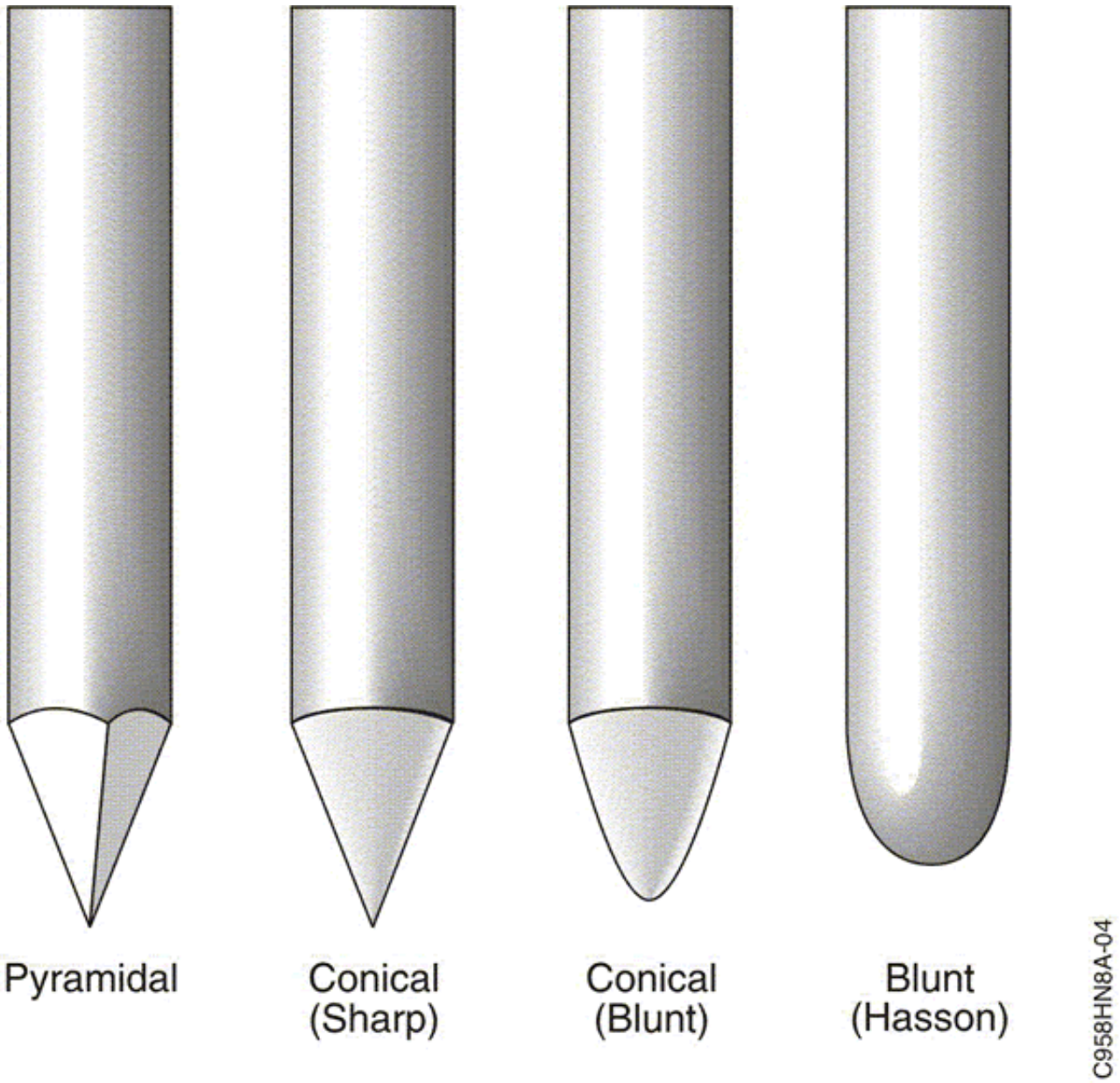


Figure 4. Some basic types of trocar tips



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