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original article

# Retained sponges in abdomen: an analysis of the judgments of the Italian Supreme Court

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SUMMARY: **Retained sponges in abdomen: an analysis of the judgments of the Italian Supreme Court.**

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*The administration of justice in Italy includes first, second and third instance. The first and second instances are represented by the Court of First Instance and the Court of Appeal: these are judgment of merit. The court of last appeal for both the civil and the criminal jurisdiction is the Court of Cassation, the Italian Supreme Court. It is a court of legitimacy that should provide for a consistent and uniform interpretation of the law and that only on points of law, not on factual evidence. The Court of Cassation can confirm the sentence of second instance, can dismiss it without referral, can deciding and closing the trial definitively, or dismiss it referring the case to the judge of merit that must decide according to the principles set out in the legitimacy. The aim of this study is to analyze the Supreme Cassation Court's judgments on the legal proceedings about retained sponges in abdomen.*

KEY WORDS: Retained sponges - Malpractice - Gossypiboma - Supreme Court judgments - Foreign body.

## Background

The administration of justice (both civil and criminal) in Italy includes first, second and third instance.

The first and second instances are represented by the Court of First Instance (*Tribunale*) and the Court of Appeal (*Corte di Appello*): these are judgment of merit.

The court of last appeal for both the civil and the criminal jurisdiction is the Court of Cassation (*Corte di Cassazione*), the Italian Supreme Court.

It is a court of legitimacy that should provide for a consistent and uniform interpretation of the law and that only on points of law, not on factual evidence. Unlike the US or the UK Supreme Courts, the Italian Court has different sections to address matters in criminal and civil litigation. When two or more sections of the Court disagree on a legal interpretation, the case is submitted to the United Section (*Sezioni Unite*).

The Court of Cassation can confirm the sentence of second instance, can dismiss it without referral, can deciding and closing the trial definitively, or dismiss it referring the case to the judge of merit that must decide according to the principles set out in the legitimacy.

In Italy to evaluate malpractice profiles there is a "fault" system that includes both civil and criminal penalties. In penal cases compared to civil ones there is a "greater rigor" in the verification of causal relationship and malpractice profiles: this is in harmony with the most recent Italian Court decisions, characterized by compelling suspect's protection in the presence of a reasonable doubt in criminal matters and by victim's protection in civil ones.

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In fact, according to Italian Law, when a conviction is proposed, there must be an absolute certainty, beyond reasonable doubt, that an offence has been committed.

While initiating a civil action is entirely dependent on the initiative of individual parties, the Italian Constitution (Article 112) states a principle of mandatory criminal action: Italy applies the principle of legality, which prescribes a criminal indictment if the prosecutor has reason to suppose a crime has been committed.

Malpractice cases in Italy are referred to the production of a physical or mental infirmity due to the fault of a heath care professional, to the instrumental lack of the health structure or to the lack of a valid informed consent.

Medical malpractice cases are mainly reviewed by the Third Civil Section and the Fourth Criminal Section of the Italian Supreme Court.

## Objective

The aim of this study is to analyze the Supreme Cassation Court's judgments on the legal proceedings about retained sponges in abdomen.

## Methods

We have analyzed the Supreme Cassation Court's judgments by using its online-database from 2013 to 2018 (http://www.italgiure.giustizia.it/sncass/).

For this research the key words used were: "garza" or "pezza" or "laparotomica" ("gauze" or "patche" or "laparotomic").

The inclusion criteria were all the Cassation Court's judgments where the retention of the sponge in the abdomen was described.

Four tables were created for entering data extrapolated by Authors:

- **Table 1**. **General characteristics of the appeal:** number of the judgment**,** the Cassation Court's section, the date of hearing and the year of publication of the judgment.
- **Table 2. Legal procedure preceding the Cassation's appeal:** parties involved *ab initio,* outcome of the first degree, outcome of the second degree.
- **Table 3. Appeal in Cassation:** appellant in Cassation, role of the healthcare professional involved, court's judgment.
- **Table 4. Characteristics of the surgery:** sex of the patient, type of surgery, characteristics of the foreign body, consequences of the retention, onset of signs and symptoms, signs and symptoms, secondary surgery.

## Results

Our research on the Supreme Cassation Court's

TABLE 1 - GENERAL CHARACTERISTICS OF THE APPEAL.

| Number of the judgment | Cassation Court's section | Date of hearing | Year of publication of the judgment |
|---|---|---|---|
| 36229 | Criminal/ 4° | 29/04/2014 | 2014 |
| 07346 | Criminal/ 4° | 08/07/2014 | 2015 |
| 27150 | Criminal/ 4° | 21/01/2015 | 2015 |
| 00334 | Civil/ 3° | 10/11/2015 | 2016 |
| 34503 | Criminal/ 4° | 25/05/2016 | 2016 |
| 17175 | Criminal/ 4° | 09/03/2017 | 2017 |
| 18045 | Civil/ 3° | 31/01/2018 | 2018 |

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TABLE 2 - LEGAL PROCEDURE PRECEDING THE CASSATION'S APPEAL.

| Number of the judgment | Cassation Court's section | Parties involved *ab initio* | Outcome of the first degree | Appellant in second degree | Outcome of the second degree |
|---|---|---|---|---|---|
| 36229 | Criminal/ 4° | -lead surgeon<br>-second surgeon<br>-surgical nurse<br>-scrub nurse | - lead surgeon : conviction for negligent personal injuries<br>- second surgeon : acquitted<br>- surgical nurse: conviction for negligent personal injuries<br>- scrub nurse: acquitted | Health professionals convicted | The first degree conviction has been confirmed |
| 07346 | Criminal / 4° | -lead surgeon<br>-surgeon<br>-surgeon<br>-surgical nurse<br>-scrub nurse | All the defendants: conviction for negligent personal injuries | Health professionals convicted | The first degree conviction has been confirmed |
| 27150 | Criminal / 4° | -lead surgeon<br>-second surgeon<br>-surgical nurse | All the defendants: conviction for negligent personal injuries | Health professionals convicted | The first degree conviction has been reversed |
| 00334 | Civil/ 3° | -insurance companies | The tribunal reject the application because there isn't proof of the encounter of the gauze in the patient's abdomen | Patient | The first degree acquittal has been confirmed |
| 34503 | Criminal / 4° | -lead surgeon<br>-second surgeon | All the defendants: conviction for negligent personal injuries | Health professionals convicted | The first degree conviction has been confirmed |
| 17175 | Criminal / 4° | -surgeon<br>-surgeon | All the defendants acquitted, because they didn't commit the crime | Prosecutor | The first degree conviction has been confirmed for 1 defendant;<br>The first degree conviction has been reversed for 1 defendant |
| 18045 | Civil / 3° | -Hospital | Biological, financial and moral damage, with permanent disability | Hospital | The first degree conviction has been confirmed, the hospital has been sentenced to pay a higher amount |

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TABLE 3 - APPEAL IN CASSATION.

| Number of the judgment | Cassation Court's section | Complainant in Cassation | Role of the healthcare professional involved | Court's Judgment |
|---|---|---|---|---|
| 36229 | Criminal/ 4° | Lead surgeon and surgical nurse convicted in the previous degrees | -lead surgeon<br>-surgical nurse | The second degree conviction has been confirmed |
| 07346 | Criminal/ 4° | Lead surgeon, surgeon, surgeon, surgical nurse and scrub nurse convicted in the previous degrees | - lead surgeon<br>-surgeon<br>- surgeon<br>- surgical nurse<br>-scrub nurse | Judgment annulled for prescription |
| 27150 | Criminal/ 4° | Patient | - lead surgeon<br>- second surgeon<br>- surgical nurse | Acquittal confirmed for the Health professionals |
| 00334 | Civil/ 3° | Patient | // | The lack of responsibility of the Health Facility has been confirmed |
| 34503 | Criminal/ 4° | Lead surgeon and second surgeon convicted in the previous degrees | - lead surgeon<br>-second surgeon | The second degree conviction has been confirmed |
| 17175 | Criminal/ 4° | Surgeon convicted in second degree | -surgeon | Judgment annulled for prescription |
| 18045 | Civil/ 3° | Patient | // | The second degree conviction has been confirmed |





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TABLE 4 - CHARACTERISTICS OF THE SURGERY.

| Number of the judgment | Cassation Court's section | Sex of the patient | Type of surgery | Radiopaque wire | Consequences of the retention | Onset of signs and symptoms | Signs and symptoms | Secondary surgery |
|---|---|---|---|---|---|---|---|---|
| 36229 | Criminal/ 4° | F | C-section | Absent | Infection, with consequent evolution in abscess and gangrene | In the first days after the surgery | Abdominal pain, with nausea and weakness | Yes |
| 07346 | Criminal/ 4° | F | Hysterectomy | Absent | Local peritonitis | Not deductible | Not deductible | Yes |
| 27150 | Criminal/ 4° | F | Laparoscopic surgery with installation of a gastric pacemaker | Not deductible | The infection caused the diastasis of the surgical wound, suppuration, swelling and bump | Infection identified in the first months of 2007 | Not deductible | Yes |
| 00334 | Civil/ 3° | F | Hysterectomy | Not deductible | Local peritonitis | Not deductible | Not deductible | Not deductible |
| 34503 | Criminal/ 4° | F | C-section | Present | Not deductible | -- | -- | Not deductible |
| 17175 | Criminal/ 4° | F | C-section | Absent (Appellate Court) | Intestinal cystic granuloma (in the Tribunal and Cassation's opinion there is no cause- and- effect relationship with the retained gauze) | In 1989 (in the Tribunal's opinion there is no cause- and- effect relationship because the temporal gap is too big) | Persistent abdominal pain | Yes |
| 18045 | Civil/ 3° | F | C-section | Not deductible | Local peritonitis | Not deductible | -- | Yes |

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online-database pointed out 10 judgments, of which 3 have been excluded: 2 because different anatomical sites were involved (1 thyroid, 1 lung) and another one because the retention wasn't described.

**General characteristics of the Supreme Cassation Court's judgments (Table 1)**
Section of the Supreme Court: among the 7 rulings involved in our study, 5 were sentenced by the 4° Criminal Division of the Supreme Court and the other 2 were sentenced by the 3° Civil Division.

**Legal procedure preceding the Cassation's appeal (Table 2)**
Reason why the patient took legal actions: in 5 cases the gauze's retention caused an infection; in 1 case it caused a granuloma; in 1 case the reason could not be inferred from the ruling.
Parties involved *ab initio*: in the 2 Civil Division's cases defendants were respectively the medical facility and the insurance companies of the hospital; with regard to the 5 Criminal cases the initially suspected subjects have been:
1. 2 surgeons, 1 surgical nurse, 1 scrub nurse
2. 3 surgeons, 1 surgical nurse, 1 scrub nurse
3. 2 surgeons, 1 surgical nurse
4. 2 surgeons.

2 surgeons.Outcome of the first degree judgment: in the 2 Civil cases in 1 case the Tribunal ruled out the defendant's fault and in 1 case recognized the defendant's fault granting a biological and financial damage suffered by the patient; in the 5 Criminal cases the defendant's fault was proven in 4 out of 5 cases.
Outcome of the second degree judgment: concerning the 2 Civil cases the Appeal Court confirmed the lack of guilt of the defendant and in 1 case the Appeal Court confirmed the defendant's guilt.
In the 5 Criminal cases, in 3 of them the first degree guilty verdict has been confirmed, in 1 case the first degree guilty verdict has been overturned with the acquittal of the accused, in 1 case the verdict of not guilty has been confirmed for 1 surgeon and overturned the not guilty verdict for the other surgeon.

**Appeal in cassation (Table 3)**
Outcome of the appeal and delivery of the judgment: with regard to the 2 Civil cases, in the case where the Appellant Court confirmed the lack of guilt of the defendant, the Cassation Court rejected the appeal and in the second case rejected the Appellant court's judgment.
In the only criminal case in which the Appellant Court excluded the healthcare professional's guilt, the Cassation Court rejected the patient's appeal. In 2 cases the healthcare professional's conviction was confirmed and in 2 cases claimed instead that the statute of limitation was expired, referring to the Civil Judge for the quantification of harm.

**Characteristics of the primary surgery (Table 4)**
Sex of the patients: in 7 out of 7 cases the patients were females.
Type of surgery: 6 gynaecological surgery (4 C-sections, 2 hysterectomies) and 1 case of bariatric surgery.
Characteristics of the foreign body: in 1 case it is a gauze with radiopaque wire, in 2 cases are not radiopaque gauzes and in 4 cases it is not clear from the sentence.
Consequences of the retention: in 3 cases the retention caused a localized peritonitis. In 1 case the patient developed an infection, with consequent evolution in abscess and gangrene. In 1 case the infection caused the diastasis of the surgical wound, suppuration, swelling and bump. In 1 case an intestinal cystic granuloma formed. In 1 case the consequences of the retention are cannot be extrapolated from the judgment.
Onset of signs and symptoms: in 3 cases the onset of the symptoms cannot be extrapolated from the judgment. In 1 case signs and symptoms appeared in the first days after the surgery. In 1 case the first signs and symptoms appeared few months after the surgery; in 1 case the signs and symptoms appeared 3 years after the event and in this case the tribunal excluded the causal link between the surgery and the symptoms. In 1 case the symptomatology is not mentioned in the judgment.
Signs/Symptoms: in 3 cases the nature of the symptoms cannot be extrapolated from the judgment. In 2 cases the symptomatology is not mentioned in the judgment. In 1 case the patient showed persistent abdominal pain. In 1 case the patient showed abdominal pain, with nausea and weakness.
Secondary surgery: in 5 cases the patient underwent a second surgery; in 1 of these cases a bowel resection with drainage of the remaining cavity was necessary. In 2 cases it is not clear from the judgment if a second surgery has been executed.

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## Discussion

Gossypiboma (from gossipium = "cotton" in Latin and boma = "place of concealment" in Kiswahili) is the retaining of a surgical sponge due to a human error. The retained surgical sponge seems to be an ongoing problem and maybe it is underestimated, since patients present with vague clinical symptoms and the diagnosis could be done several years after the initial surgical procedure. The incidence of this problem cannot be determined exactly because it is seldom reported, in view of its medico-legal implications. However, an estimation suggests that a foreign body is retained in 1 of every 1000 to 1500 abdominal surgeries. With regard to the clinical presentation, patients with an abdominal sponge retention often present with pain, discomfort, palpable mass or unexplained fever; the irritation of bowel loops, bladder or rectum can lead to vomiting, diarrhoea, hematuria, dysuria, tenesmus and other systemic complaints (1).

The aim of this study is to analyze the Supreme Cassation Court's judgments on the legal proceedings about retained sponges in the abdomen.

The research has been carried out on the Supreme Cassation Court's judgments online-database looking for the judgments from the 2013 to the 2018. This has enabled to identify 7 judgments of which 2 were sentenced by the 3° Civil Division and the other 5 were sentenced by the 4° Criminal Division of the Supreme Court.

The 7 rulings involved in our study all concerned female sex patients, of whom 6 had gynecological surgery (4 caesarean sections and 2 hysterectomies).

The alleged damage by the patients due to the gauze's retention was mostly infectious. In one case the alleged damage was a granuloma, in which the Court excluded the healthcare's fault because the patient did not prove the harm.

No patients died because of the gauze retention.

With regard to the Supreme Cassation Court's judgments we remind that in Italy there is a "fault" type system based on the demonstration of the healthcare's guilt.

The first Civil case was about a woman who underwent an hysterectomy. The legal proceeding, that involved the Tribunal and the Court of Appeal, ruled out the fault of the health facility and rejected the claim for compensation, because of the lack of proof of the retention of the gauze in the patient's abdomen and her appeal was declared inadmissible by the Supreme Cassation Court.

The second Civil case was about a woman who underwent a Caesarian section. The long legal proceeding, that involved the Tribunal, the Court of Appeal and the Court of Cassation, established the fault of the health facility and accepted the request for compensation.

In the only criminal case where the Appeal Court ruled out the healthcare professional's fault, the action brought by the patient has been also rejected by the Supreme Cassation Court, confirming the healthcare professional's acquittal.

In 2 cases the Supreme Cassation Court confirmed the healthcare professional's conviction and in another 2 cases the Supreme Cassation Court expunged the crime as the statute of limitation expired, referring to the Civil Judge for the quantification of harm. In those cases the Supreme Cassation Court's judgments found guilty both the nurses and the surgeons.

In fact, lately there has been a paradigm shift, with the physician's work moving from an individualistic work to a more teamwork-oriented approach.

A med-surge team activity is when Physicians and other healthcare professionals work together to achieve a common target. This kind of approach is now widespread in all the types of surgery and more health professionals are involved in the team (2).

This kind of activity heralded important judicial problems over time, because it was difficult to identify the exact role of each fellow of the team (3).

Indeed those are cases in which a multiple operators engage in risky behavior for the patient's life.

It has been raised the issue if every team's component, in addition to its role, has to observe the other's components behavior and if it has to be held responsible of negligent behavior if another team's member makes a mistake.

It has been hypothesized that if the behavior of the individual health professional is superimposed to the other's members behavior, it will have to rely to the principle of legitimate expectations, in which every member of the team hasn't to be forced to act based on the other members conduct.

This study have shown that the Italian Justice blames not only the surgical nurse, who is responsi-

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ble for the gauze's count, but also the surgeon that has to supervise on the work of the other members of the team.To eliminate the risk of gossypibomas, all sponges should be counted at least twice (once preoperatively and once postoperatively), avoiding the use of small sponges during laparotomy and using only sponges with radiopaque markers, allowing the sponges to be seen by X-ray detection (4).

It may also be useful the use of bar-coded sponges which allows for an automated counting of the surgical sponges. Such technology has been tested and has shown an improved detection of miscounted and misplaced sponges, while being well tolerated by surgical staff members (5).

## Conclusions

Although the decisions of the Court of Cassation cannot be regarded as a straightforward indicator of the medical malpractice litigation in Italy, they nevertheless prove informative given the 'production' of precedents.

The first step towards a conviction requires that the patient proves the retention of the gauze in the abdomen.

The Italian Justice blames not only the surgical nurse, who is responsible for the gauze's count, but also the surgeon that has to supervise on the work of the other members of the team.

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