Objectives
This continuing dental education course has been written to discuss the etiology and management of complications associated with post-operative extractions. Techniques to manage difficulties occurring immediate post-operative and days after will be discussed. Topics include: causes of difficult extractions, the healing process, high risk patients, management of bleeding, hemostatic agents, dry sockets, prevention of dry sockets, and treatment of dry sockets. Surgical techniques and pain management will not be discussed in this course.

Introduction
Difficulties with extractions are unpredictable. Having a thorough medical history prior to surgery will allow the surgeon to better deal with complications that may arise. Be certain to always follow proper surgical techniques, and know your limitations prior to beginning any extraction. If and when difficulties develop, it is always recommended to explain the situation to the patient.

Factors That Increase Extraction Difficulty
In most instances, extraction of non-impacted teeth is a routine dental procedure. Extraction difficulty increases when the following conditions exist: strong supporting tissue, difficult root morphology (divergent, hooked, locked, ankylosed, geminated, misshaped or exhibiting hypercementosis), teeth containing weakened coronal surfaces due to large restorations, teeth that have been abraded or exhibit abfractions or deep caries, desiccated or brittle teeth associated with endodontic treatment, patients experiencing inflammatory disorders associated with alveolar bone (including Paget’s disease), patients with radionecrotic bone caused by radiation therapy, and patients with limited opening or trismus.

Normal Healing Process
Immediately after teeth are extracted, blood flowing from alveolar bone and gingiva begins to clot. The clot functions by preventing debris, food, and other irritants from entering the extraction site. It also protects the underlying bone from bacteria and finally acts as a supporting system in which granulation tissue develops. Tissue damage provokes the inflammatory reaction, and the vessels of the socket expand. Leucocytes and fibroblasts invade from the surrounding connective tissues until the clot is replaced by granulation tissue. Leucocytes gradually digest the clot, while epithelium begins to proliferate over the surface during the second week post-operatively. This eventually forms a complete protective covering.

During this time, there is an increased blood supply to the socket which is associated with resorption of the dense lamina dura by osteoclasts. Small fragments of bone which have lost their blood supply are encapsulated by osteoclasts and eventually pushed to the surface.
or resorbed. Approximately one month after an extraction, coarse, woven bone is then laid down by osteoblasts. Trabecular bone then follows, until the normal pattern of the alveolus restored. Finally, compact bone forms over the surface of the alveolus, and remodeling continues as the bone shrinks.

**Bleeding Challenges**

Bleeding challenges sometime present themselves due to the nature of the body’s hematologic system. The high vascularization of the head and neck region is both friend and foe to the dental surgeon. Once a tooth is extracted, direct primary wound closure is sometimes impossible, due to the lack of soft tissues that leave large openings in the alveolus. Unlike other wounds or surgical openings, there is an inability to apply and sustain direct pressure to the socket of an extracted tooth. Other forces exist to even complicate things further, such as disruptive forces from tongue motion, passage of food, and normal speech. Salivary enzymes also interfere with blood clotting and the processes that follow in the evolution of the clot.

**Preventing Problems and Health History**

A thorough medical history should be taken, including questions regarding bleeding problems. Some conditions that may prolong bleeding are non-alcoholic liver disease (primarily hepatitis), and hypertension. Patients with known bleeding disorders should only be treated by oral/maxillofacial surgeons, or dentists that have had extensive training in managing medically compromised patients. Techniques to manage bleeding may employ the administration of blood transfusions containing adequate factor replacement which will allow for hemostasis. The health history should include questions that discover bleeding problems associated with minor scrapes and cuts. Family medical history is also important in order to detect possible genetic diseases that patients are unaware of potentially having. Complete and current medication lists should be documented and checked against references that may indicate side effects. It is also advisable that patients taking extensive medications receive clearance to undergo surgery from their physician.

Many drugs interfere with coagulation. There are five groups of drugs known to promote bleeding: aspirin, broad-spectrum antibiotics, anticoagulants, alcohol, and chemotherapeutic agents. Aspirin and aspirin containing preparations interfere with platelet function and bleeding time. Anticoagulant drugs speak for themselves. Broad-spectrum antibiotics decrease vitamin K production which is necessary for coagulation factors produced in the liver. Chronic alcohol abuse can lead to liver cirrhosis and decreased production of liver-dependent coagulation factors. Chemotherapeutic agents that interfere with the hematopoietic system can reduce the number of circulating platelets. Patients who are known or suspected to have bleeding disorders should be evaluated and laboratory tested before surgery. Prothrombin time (PT) can be used.

**Bleeding**

Once the tooth is completely removed, the wound should be properly cleaned. It should be inspected for the presence of any specific bleeding arteries or other potential anomalies. If and when arteries exist in the soft tissue, they should be controlled with direct pressure by clamping and eventual ligation with resorbable suture. If no arteries exist in the extraction field, complete hemostatic control can usually be maintained for most procedures by using direct pressure over the area of soft tissue for approximately five minutes.

Bleeding from isolated vessels within the bone can occur. Treatment involves crushing the foramen with the closed ends of the hemostat. This will usually occlude the bleeding vessel. Once the foramen is crushed, the socket should be covered with a damp 2x2 inch gauze sponge that has been folded to fit directly into the extraction site. The patient should be instructed to bite down firmly on this damp gauze sponge for at least 30 minutes. Do not dismiss the patient from the office until hemostasis has been achieved. Check the patient’s extraction socket approximately fifteen minutes after the completion of surgery. The patient should open the mouth widely, the gauze should be removed, and the area should be inspected carefully for any persistent bleeding or oozing. Replace the gauze with a new piece and repeat in thirty
minutes. If bleeding persists and inspection reveals no arterial bleeding, the surgeon should immediately place a hemostat into the socket. After placing the hemostatic agent, a gauze sponge should be placed over the top of the socket and is held with pressure.

**Hemostatic Agents**

The most commonly used, least expensive hemostatic agent is absorbable gelatin sponge (Gelfoam®, Pfizer). Gelfoam sterile compressed sponge is a pliable surgical hemostat prepared from specially treated purified gelatin solution. It is capable of absorbing and holding within its meshes many times its weight in whole blood. It is designed to be inserted in the dry state, and functions wonderfully as a hemostatic agent. Gelfoam® forms a scaffold for the formation of a blood clot. Gelfoam has been used to aid in primary closure for large extraction sites, and is placed into the socket and retained with a suture.

Oxidized regenerated methylcellulose (Sur- gice®, Johnson & Johnson) is another hemostat used in dental surgery. It binds platelets and chemically precipitates fibrin. It is placed into the socket and sutured. It can not be mixed with thrombin. Topical thrombin (Thrombo- stat®, Pfizer) is derived from bovine thrombin (5,000 units). Thrombin bypasses all steps in the coagulation cascade and helps to convert fibrinogen to fibrin, which forms the clot. It is usually saturated into Gelfoam and inserted into the tooth socket when needed.

Collagen type products can also be used to help control bleeding, by promoting platelet aggregation and thereby accelerating blood coagulation. Microfibular collagen (Avitene®, Davol) is a fibular material that is loose and fluffy but able to be packed. Collaplug/Collatape (Sulzer Calcitek) are more highly crosslinked collagen and can also be packed. Collagen type products stimulate platelet adherence which helps stabilize the clot, but are much more expensive and usually not used. It is important to note that when using hemostats, the materials are placed in the socket and sutured to the gingival margin surrounding the extraction site. This will assure that they are secure.

**Secondary Bleeding**

Patients will sometimes return to the office with secondary bleeding, caused in most cases by improper adherence of postoperative instructions. In these cases, the extraction site should be cleared of all blood and saliva using suction. The dental surgeon should visualize the bleeding site to carefully determine the source of bleeding. If it is determined that the bleeding is generalized, the site should be covered with a folded, damp gauze sponge, and held in place with firm pressure by either the dentist or dental auxiliary for at least five minutes. This measure is sufficient to control most bleeding. If five minutes of this treatment does not control the bleeding, the dental surgeon must administer a local anesthetic so that the socket can be treated more aggressively. Block techniques are encouraged instead of local infiltrations. If infiltration is used, and the anesthetic contains epinephrine, temporary vasoconstriction may be achieved and create the impression that the bleeding has stopped permanently. Be cautious.

Once anesthesia has been achieved, gently curette the tooth extraction socket and suction all areas of old blood clot. The specific area of bleeding should be identified. The same measures described for control of primary bleeding should be followed. The use of Gelfoam® (absorbable gelatin sponge) saturated with topical thrombin, then sutured, is an effective way to stop bleeding. Reinforcement should be repeated with the application of firm pressure from a small, damp gauze sponge. In many situations, Gelfoam® and gauze sponge pressure is adequate.

Before the patient with secondary bleeding is discharged to go home, the clinician should monitor the patient for at least 30 minutes to ensure that adequate hemostatic control has been achieved. Be certain to give the patient specific instructions on how to apply gauze packs and pressure directly to the bleeding site should additional bleeding occur.

Subcutaneous tissue spaces may become collection areas for bleeding associated with some extractions. When this occurs, overlying soft tissue areas will appear bruised two to five
days after the surgery. This bruising is called ecchymosis. Ecchymosis occurs more frequently in elderly patients. Ecchymosis may extend into the neck and as far as the upper anterior chest. Ecchymosis does not increase the potential for infection or other sequelae. Elderly patients should be warned that there is the potential for ecchymosis. Reducing trauma is the best way to prevent ecchymosis. Moist heat may be applied to speed up the recovery.

**Delayed Healing**

Normal healing of extraction sites are dependent on blood clot formation and the progression of that clot to a reorganized matrix preceding the formation of bone. It is uncommon for the blood clot to fail to form except in cases where there is a loss or interruption of the local blood supply.

It is now thought that infection is the most common cause delaying wound healing. Signs and symptoms associated with infection can include fever, swelling, and erythema. Careful asepsis and thorough wound debridement should be performed after surgery. Irrigate bone copiously with saline to aid in the removal of foreign debris. Patients prone to infection should be given postoperative antibiotics to reduce infection blow-ups.

Wound dehiscence should be avoided by following good surgical techniques. Leaving unsupported soft tissue flaps can often lead to tissue sagging and separation along the incision line. Suturing wounds under tension can cause ischemia of flap margins, which may lead to tissue necrosis.

Other factors, though rarely seen, that can delay healing are: prolonged bleeding due to clotting defects, formation of an oro-antral fistulas, proliferation of malignant tumors, radiation therapy, immunosupression due to corticosteroid use, dietary deficiencies including but not limited to vitamin C, and overall immune system disorders.

**Dry Socket Identification**

Dry socket delays the healing of the extraction site and surrounding bone. Dry socket can be diagnosed by looking for certain symptoms. Moderate to severe localized pain near the extraction site developing on or after the third or fourth day post extraction is a sure giveaway. Patients can state that there is an apparent improvement in discomfort on the second day only to be followed by a sudden worsening of the pain. The pain is moderate to severe, consisting of a dull aching sensation, usually throbbing which radiates to the ear examination will reveal an empty socket, exposed bone surfaces, with a partially or completely lost blood clot. A bad odor and taste may or may not be present. Loss of sleep is caused by pain the previous night, and control of the pain is very difficult even with narcotic analgesics. Dramatic relief within an hour can be seen after placement of dry socket products.

**Incidence**

The incidence of dry socket has been reported in the literature by many investigators, and ranges between 0.5% - 68.4% depending on which study is reviewed. The average is approximately 3% of all extractions. It has been shown that the occurrence of dry socket is between 9-30% in impacted mandibular third molars. The condition occurs two times as often after single extractions as compared to multiple extractions completed during the same time frame.

**Etiology and Predisposing Factors**

Fibrinolysis is the breakdown or failure of normal clot formation due to high levels of fibrinolytic or proteolytic activity in and around the socket. Fibrinolytic activity results in lysis of the blood clot and subsequent exposure of the bone.

Fibrodylisis is the breakdown or failure of normal clot formation due to high levels of fibrinolytic or proteolytic activity in and around the socket. Fibrinolytic activity results in lysis of the blood clot and subsequent exposure of the bone. Mandibular teeth are most commonly associated with dry socket. Sites affected are ranked in order from highest to lowest as follows: lower molars, upper molars, premolars, canines, incisors. Studies have demonstrated that the more difficult the extraction, the higher the chance of dry socket. It has also been demonstrated that less-experienced dental surgeons had a higher incidence of dry socket in lower third molars. The peak age for dry sockets is 30-34 years. Most reported cases occur between the ages of 20 and 40.
Bacteria, especially anaerobic, have been linked to the formation of dry sockets. Investigators have found strains of Streptococci, Fusobacterium necrophorum, Treponema denticola, and bacteroides within extraction sites.

Studies have shown that smokers are four times more likely to develop third-molar dry sockets than nonsmokers. This may be related to creation of suction when inhaling, contamination of the socket with smoke, or increased temperatures in the oral cavity. Researchers have identified that women have a 20% better chance to develop dry socket than males. Oral contraceptives are also linked to higher incidence of dry socket along with post-extraction trismus and pain.

Patients with uncontrolled diabetes mellitus have a greater incidence of dry socket and should be monitored carefully.

Prevention of Dry Socket
Developing cures and techniques that will prevent dry socket has been a topic of interest in oral surgery for many years. Well-controlled studies indicate that the incidence of dry socket after mandibular third-molar surgery can be reduced. Proper surgical techniques should include thorough debriding and irrigation of the extraction site with large quantities of saline. This should be first on your list in controlling the incidence of dry socket.

The incidence of dry socket may be decreased by preoperative and postoperative rinsing with antimicrobial mouth rinses, such as chlorhexidine gluconate (Peridex®). A study was performed involving preoperative prophylaxis in conjunction with chlorhexidine gluconate 0.2 percent rinse. Incidence of dry socket was decreased to some degree. Use of other medicaments such as Betadine Mouthwash may also be useful in reducing bacterial loads prior to surgery. Use of topically placed antibiotics administered within the extraction site immediately after completion of the extraction has been the most widely studied modality to reduce dry socket. Antibiotics such as clindamycin or tetracycline have been successfully used to help to decrease the incidence of dry socket in mandibular third molars.

Treating Dry Socket
If dry socket (alveolar osteitis) should arise, treatment should be focused on relieving pain. If the patient does not receive treatment for the relief of pain, the healing process will

Tetracycline
One study shows that placement of tetracycline in a suspension with a few drops of saline dipped in a square of Gelfoam® significantly reduce the incidence of dry socket when used as a dressing after impacted mandibular third molar extractions. This study supports findings reported by other authors. Both the tetracycline studies have strikingly similar findings showing an average of a 3.8% incidence of dry socket when using tetracycline prophylactically.

Another study looked at neomycin, bacitracin, and tetracycline combined with saline, soaked in Gelfoam, and placed in the extraction socket of third molars. Results demonstrated that tetracycline was far more effective than either neomycin or bacitracin (combined with Gelfoam®) in decreasing dry socket.

Clindamycin
Trieger studied the effects of a 1x1 cm square of Gelfoam soaked with 1 ml of clindamycin phosphate solution (150 milligrams/milliliter) compared to controls using no clindamycin. Results indicated that out of 172 impacted molar sites, only 7 dry sockets occurred, all of which were control sites that were not exposed to clindamycin. Clindamycin is especially preferred as the drug of choice in the prevention of dry socket due to its antianaerobic properties.

Chapnick performed a study of 520 mandibular teeth in 270 patients. Sites were irrigated with Betadine (Purdue Frederick) prior to placement of clindamycin. One site received Gelfoam soaked in clindamycin, the other received Gelfoam without clindamycin. Results indicated that there was a significant decrease in dry socket in the sites that received Gelfoam soaked in clindamycin. These studies demonstrate reduction in dry socket is as low as 3% from 36% when antibiotic medicaments were placed. There is evidence that bacteria, through mechanisms not yet understood, play a role in the fibrinolytic phenomenon of dry socket.

T Treating Dry Socket
If dry socket (alveolar osteitis) should arise, treatment should be focused on relieving pain. If the patient does not receive treatment for the relief of pain, the healing process will
eventually resolve itself with no difference in time as if treated. Treatment should begin by gently irrigating with saline, and the insertion of a medicated dressing. Do not curette the socket because this will increase the amount of exposed bone and the pain, and remove parts of the blood clot that have not been lysed. The socket should then be carefully suctioned of all excess saline. Then, a small piece of gelatin sponge or gauze soaked with the medication should be placed. This may need to be repeated for 3-6 days depending on the severity of the pain. At each visit, the socket will need to be irrigated, and insertion of the medicated dressing repeated. Medicaments used to treat dry socket may contain a combination of the following ingredients: bone pain relievers (Eugenol, benzocaine), anti-microbials (iodoform), and carrying vehicles (balsam of Peru, Penghawar).

Dry socket pastes and liquids (various manufacturers) can be used and placed directly in the socket alone or using absorbable products such as Gelfoam. Alvyjel (Septodont) is a fibrous product that can be placed and left in the socket. Iodoform Packing Gauze (Johnson & Johnson) is also available. Once placed in the extraction socket, the patient will experience profound relief from pain within 5 minutes. Generally, anesthesia is not recommended when placing these products.

**Conclusion**

This continuing dental education course was designed to review the most common complications, etiology, and treatment modalities found in the literature to manage complications associated with dry socket. Techniques and products that were presented were most commonly used in the literature. Other techniques exist that may be as effective as the ones discussed here. Further research is needed to provide answers to questions associated with post extraction difficulties.

**References**


Continuing Dental Education Questions

1. Having a thorough medical history prior to surgery will allow the surgeon to better deal with complications that may arise. Be certain to always follow proper surgical techniques, and know your limitations prior to beginning any extraction.
   a. The first statement is True. The second statement is True.
   b. The first statement is True. The second statement is False.
   c. The first statement is False. The second statement is True.
   d. The first statement is False. The second statement is False.

2. If and when difficulties develop, it is always recommended to explain the situation to the patient.
   a. True
   b. False

3. Extraction difficulty increases when the following conditions exist except
   a. strong supporting tissue
   b. difficult root morphology
   c. teeth containing weakened coronal surfaces
   d. desiccated teeth
   e. none of the above

4. The clot functions by
   a. Preventing debris, food, and other irritants from entering the extraction site.
   b. Protecting the underlying bone from bacteria.
   c. Acts as a supporting system in which granulation tissue develops.
   d. All of the above

5. The clot is immediately replaced by
   a. granulation tissue
   b. woven bone
   c. cancellous bone
   d. all of the above

6. There is an increased blood supply to the socket which is associated with resorption of the dense lamina dura by
   a. Leucocytes
   b. Fibroblast
   c. Osteoclasts
   d. Osteoblasts

7. Which of the following is not true regarding small fragments of bone which have lost their blood supply?
   a. Can be pushed to the surface and expelled
   b. Can be encapsulated by osteoclasts
   c. Can be suctioned out during curratage
   d. Can be converted to vascularized bone
   e. None of the above

8. Approximately how long does it take for coarse woven bone to be laid down by osteoblasts?
   a. One month after an extraction
   b. One week after an extraction
   c. One day after an extraction
   d. Three months after an extraction

9. Woven bone follows trabecular bone, until the normal pattern of the alveolus is restored. Finally, compact bone forms over the surface of the alveolus, and remodeling continues as the bone shrinks.
   a. The first statement is True. The second statement is True.
   b. The first statement is True. The second statement is False.
   c. The first statement is False. The second statement is True.
   d. The first statement is False. The second statement is False.

10. Once a tooth is extracted, direct primary wound closure is sometimes impossible, and there usually is an inability to apply and sustain direct pressure to the socket of an extracted tooth.
    a. True
    b. False

11. What forces exist to complicate clotting?
    a. Disruptive forces from tongue motion
    b. Passage of food
    c. Normal speech
    d. All of the above

12. Which is not a condition that may prolong bleeding?
    a. Primarily hepatitis
    b. Hypertension
    c. Osteoporosis
    d. None of the above

13. There are how many groups of drugs known to promote bleeding?
    a. 3
    b. 4
    c. 2
    d. 5

14. Broad-spectrum antibiotics decrease production of what vitamin which is necessary for coagulation factors to be produced in the liver?
    a. Vitamin A
    b. Vitamin D
    c. Vitamin E
    d. Vitamin K

15. Chronic alcohol abuse can lead to liver cirrhosis and decreased production of
    a. Liver-dependent coagulation factors
    b. Collagenase
    c. Nitrates
    d. All of the above

16. If no arteries exist in the extraction field, complete hemostatic control can usually be maintained for most procedures by using
    a. Rinsing with warm water for five minutes
    b. Finding arteries deep in the bone.
    c. Using direct pressure over the area of soft tissue for approximately five minutes
    d. None of the above

17. What is the authors recommended treatment when bleeding from isolated vessels within the bone occur?
    a. Crushing the vessel foramen
    b. Apply a thrombin
    c. Cauterize the vessel
    d. All of the above

Continued on the next page...
18. What is the most commonly used, least expensive hemostatic agent?
   a. Absorbable gelatin sponge
   b. Collagen tape
   c. Oxidized regenerated methylcellulose
   d. Iodoform Gauze

19. Gelatin sponge forms a scaffold for the formation of
   a. exudite
   b. osseous bone
   c. a blood clot
   d. none of the above

20. Topical thrombin (Thrombostat® Pfizer) is derived from
   a. Equine thrombin
   b. Bovine thrombin
   c. Porcine thrombin
   d. Feline thrombin

21. Thrombin bypasses all steps in the coagulation cascade and helps to convert fibrinogen to
   a. Cancellus bone
   b. Collagen
   c. Fibrin
   d. None of the above

22. It is recommended that block techniques are encouraged instead of local infiltrations when treating secondary bleeding.
   a. True
   b. False

23. Ecchymosis can appear _____ after the surgery.
   a. Immediately
   b. 1-2 days after surgery
   c. 2-5 days after surgery
   d. 3-6 days after surgery

24. Ecchymosis occurs more frequently in what patient population?
   a. Children
   b. Teenagers
   c. Elderly Patients
   d. Young Adults

25. Signs and symptoms associated with infection can include
   a. Fever
   b. Swelling
   c. Erythema
   d. All of the above

26. Which is not a factor that can delay healing?
   a. Clotting defects
   b. Formation of an oro-antral fistula
   c. Proliferation of malignant tumors
   d. Corticosteroid use
   e. None of the above

27. Which is not a symptom of dry socket?
   a. Localized pain
   b. Bad odor
   c. Bad taste
   d. Dramatic relief when treated
   e. None of the above

28. The incidence of dry socket on average is approximately what percent of all extractions?
   a. 2%
   b. 1%
   c. 4%
   d. 3%

29. What is the occurrence of dry socket in impacted mandibular third molars.
   a. 9-30%
   b. 10-40%
   c. 11-50%
   d. 12-60%

30. Which teeth are most commonly associated with dry socket?
   a. Upper molars
   b. Lower molars
   c. Premolars
   d. Canines, incisors.

31. Studies have demonstrated extraction difficulty is not related to the chance of dry socket.
   a. True
   b. False

32. It has also been demonstrated that less-experienced dental surgeons had a higher incidence of dry socket in lower third molars.
   a. True
   b. False

33. What is the peak patient age for dry sockets?
   a. 15-19 years old
   b. 20-29 years old
   c. 30-34 years old
   d. 35-40 years old

34. Smokers are how many more times likely to develop third molar dry sockets than nonsmokers?
   a. Four
   b. Three
   c. Two
   d. None

35. Researchers have identified that women have a higher chance to develop dry socket than males. How much higher is the incidence in women?
   a. 10%
   b. 20%
   c. 30%
   d. 35%

36. What are the two most studied antibiotics that have been successfully used to help to decrease the incidence of dry socket in mandibular third molars?
   a. Cefzil & Cipro
   b. Penicillan & Biaxin
   c. Clindamycin & Zithromax
   d. Clindamycin & Tetracycline

37. When antibiotic medicaments were placed in dry socket studies, there was a reduction from
   a. 34- 1%
   b. 35- 2%
   c. 36- 3%
   d. 37-4%
Etiology, Prevention, and Management of Post Extraction Complications

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COURSE EVALUATION
We encourage participant feedback pertaining to all courses. Please be sure to complete the attached survey included with the answer sheet.

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Michael Florman, DDS

EDUCATIONAL OBJECTIVES
This continuing dental education course has been written to discuss the etiology and management of complications associated with post-operative extractions. Techniques to manage difficulties occurring immediate post-operative and days after will be discussed.

INSTRUCTIONS
All questions should have only one answer. Grading of this examination is done manually. Participants will receive confirmation of passing by receipt of a certificate. Certificates will be mailed within three weeks after receiving examination.

SPONSOR/PROVIDER
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10. A B C D E 29. A B C D E
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16. A B C D E 35. A B C D E
17. A B C D E 36. A B C D E
18. A B C D E 37. A B C D E
19. A B C D E
DESCRIPTION
GELFOAM® Sterile Sponge is a medical device intended for application to bleeding surfaces as a hemostatic. It is a water-insoluble, off-white, nonelastic, porous, pliable product prepared from purified pork skin Gelatin USP Granules and Water for Injection. USP. It may be cut without fraying and is able to absorb and hold within its interstices, many times its weight of blood and other fluids.

DIRECTIONS FOR USE
Sterile technique should always be used to remove GELFOAM Sterile Sponge from its packaging. Cut to the desired size, a piece of GELFOAM, either dry or saturated with sterile, isotonic sodium chloride solution (sterile saline), can be applied with pressure directly to the bleeding site. When applied dry, a single piece of GELFOAM should be manually compressed before application to the bleeding site, and then held in place with moderate pressure until hemostasis results. When used with sterile saline, GELFOAM should be first immersed in the solution and then withdrawn, squeezed between gloved fingers to expel air bubbles, and then replaced in saline until needed. The GELFOAM sponge should promptly return to its original size and shape in the solution. If it does not, it should be removed again and kneaded vigorously until all air is expelled and it expands to its original size and shape when returned to the sterile saline.

GELFOAM is used wet or blotted to dampness on gauze before application to the bleeding site. It should be held in place with moderate pressure, using a pledget of cotton or small gauze sponge until hemostasis results. Removal of the pledget or gauze is made easier by wetting it with a few drops of sterile saline, to prevent pulling up the GELFOAM which may then be removed with a forceps. Use of suction applied over the pledget of cotton or gauze to draw blood into the GELFOAM is unnecessary, as the GELFOAM will draw up sufficient blood by capillary action. The first application of GELFOAM will usually control bleeding, but if not, additional applications may be made using fresh pieces, prepared as described above. Use only the minimum amount of GELFOAM, cut to appropriate size, necessary to produce hemostasis. The GELFOAM may be left in place at the bleeding site, when necessary. Since GELFOAM causes little more cellular reaction than does the blood clot, the wound may be closed over it. GELFOAM may be left in place when applied to mucosal surfaces until it liquefies. For use with thrombin, consult the thrombin insert for complete prescribing information.

CONTRAINdications
GELFOAM Sterile Sponge should not be used in closure of skin incisions because it may interfere with healing of the skin edges. This is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing. GELFOAM should not be placed in intravascular compartments, because of the risk of embolization.

WARNINGS
GELFOAM Sterile Sponge is not intended as a substitute for meticulous surgical technique and the proper application of sutures, or other conventional procedures for hemostasis. GELFOAM is supplied as a sterile product and cannot be resterilized. Unused, opened envelopes of GELFOAM should be discarded.

Only the minimum amount of GELFOAM necessary to achieve hemostasis should be used. Once hemostasis is attained, excess GELFOAM should be carefully removed. The use of GELFOAM is not recommended in the presence of infection. GELFOAM should be used with caution in contaminated areas of the body. If signs of infection or abscesses develop where GELFOAM has been positioned, reoperation may be necessary in order to remove the infected material and allow drainage. Although the safety and efficacy of the combined use of GELFOAM with other agents such as topical thrombin has not been evaluated in Pharmacon-controlled clinical trials, if in the judgement of the physician, concurrent use of topical thrombin is medically advisable, the product literature for that agent should be consulted for complete prescribing information.

While packing a cavity for hemostasis is sometimes surgically indicated, GELFOAM should not be used in this manner unless excess product needed to maintain hemostasis is removed. Whenever possible, it should be removed after use in laminaeurotic procedures and from foramina in bone, once hemostasis is achieved. This is because GELFOAM may swell to its original size on absorbing fluids, and produce nerve damage by pressure within confined bony spaces. The packing or wadding of GELFOAM, particularly within bony cavities, should be avoided, since swelling to original size may interfere with normal function and/or possibly result in compression of the tissues of surrounding bony spaces.

PRECAUTIONS
Use only the minimum amount of GELFOAM Sterile Sponge needed for hemostasis, holding it at the site until bleeding stops, then removing the excess. GELFOAM should be used for controlling postpartum hemorrhage or menorrhagia. It has been demonstrated that fragments of another hemostatic agent, microfibrillar collagen, pass through the 40µ transfusion filters of blood scavenging systems. GELFOAM should not be used in conjunction with these blood scavenging circuits since the safety of this use has not been evaluated in controlled clinical trials.

Microfibrillar collagen has been reported to reduce the strength of methylmethacrylate adhesives used to attach prostatic devices to bone surfaces. As a precaution, GELFOAM should not be used in conjunction with such adhesives.

ADVERSE REACTIONS
There have been reports of fever associated with the use of GELFOAM. Without demonstrable infection. GELFOAM Sterile Sponge may serve as a nidus for infection and abscess formation, and has been reported to potentiate bacterial growth. Giantcell granulomas have been reported at the implantation site of absorbable gelatin product in the brain, as has compression of the brain and spinal cord resulting from the accumulation of sterile fluid.10

Foreign body reactions, ‘incapsulation’ of fluid and hemotoma have also been reported. When GELFOAM was used in laminaeurotic operations, multiple neurologic events were reported, including but not limited to cauda equina syndrome, spinal diencephalic, meningitis, arachnoiditis, headaches, parotidomas, pain, bladder and bowel dysfunction, and impotence.

Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin products were used in severed tendon repair. Toxic shock syndrome has been reported in association with the use of GELFOAM in nasal surgery.

Fever, failure of absorption, and hearing loss have been reported in association with the use of GELFOAM during tympanoplasty.

ADVERSE REACTIONS REPORTED FROM UNAPPROVED USES
GELFOAM is not recommended for use other than as an adjunct for hemostasis.

While some adverse medical events following the unapproved use of GELFOAM have been reported to Pharmacia & Upjohn Company (see ADVERSE REACTIONS), other hazards associated with the use of GELFOAM during tympanoplasty.

HOW SUPPLIED
GELFOAM Sterile Sponge is supplied in a sterile envelope enclosed in an outer peelable envelope. Sterility of the product is assured unless the outer envelope has been damaged or opened. It is available in the following sizes:

Sponge-Size 12—7.7 mm Box of 12 09-0315-03
Sponge-Size 50 Box of 4 09-0323-01
Sponge-Size 100 Box of 6 09-0342-01
Sponge-Size 200 Box of 6 09-0349-01
Pack-Size 6 cm Box of 6 09-0371-01

REFERENCES

GELFOAM® absorbable gelatin sponge, USP

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GELFOAM® helps ensure

THE BLOOD STOPS HERE.

Convenient, pliable aid to hemostasis

- Retains many times its weight in blood
- Complete absorption in tissue without excessive scarring
- Versatile and easy to use

Call your supplier today!
To order, please contact your dental supplier or call Pfizer at 1-800-533-4535

INDICATIONS AND USAGE
Hemostasis: In oral and dental surgery, GELFOAM Dental Sponges are an aid in providing hemostasis. GELFOAM may be used either dry or moistened, depending upon conditions present at operation and preference of the surgeon. Isotonic saline is suitable for use with GELFOAM.
CONTRAINdications: GELFOAM Dental Sponges should not be used in closure of skin incisions because they may interfere with the healing of skin edges.
ADVERSE REACTIONS: Although sterile, GELFOAM Dental Sponges may form a nidus of infection and abscess.

Available again! Revised packaging!

Gelfoam®
Dental Sponge (size 4)
absorbable gelatin sponge