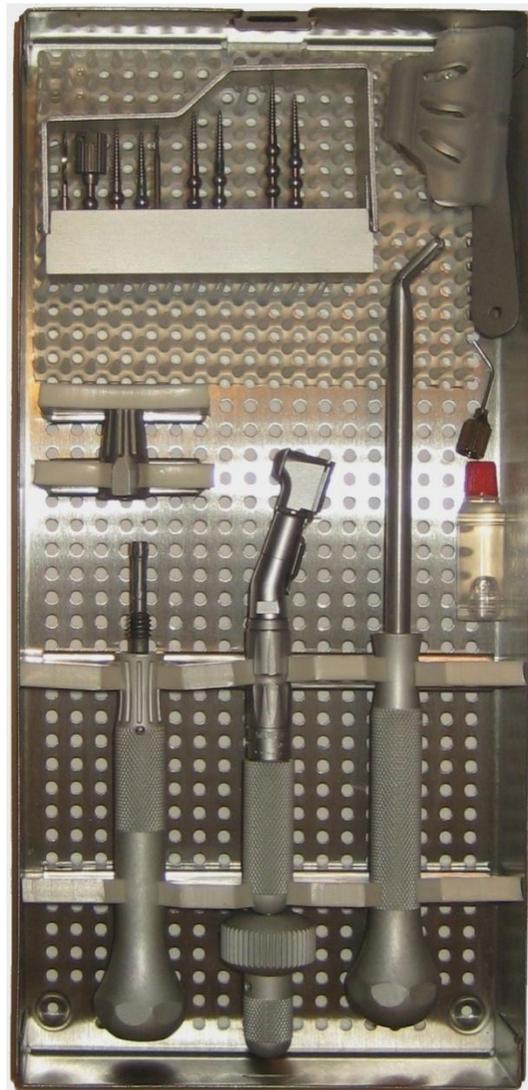


# SAPIAN ROOT REMOVER SYSTEM

## USER GUIDE AND INSTRUCTIONS



These written instructions can also be viewed and/or printed from  
<http://www.SapianRD.com/files/sapianrootremoverinstructions.pdf>



# SAPIAN ROOT REMOVER SYSTEM

## USER GUIDE AND INSTRUCTIONS

By Schubert Sopian, DDS and Randall Billington, Esq.  
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Patent Pending

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## INDICATIONS

The photos below show examples of cases in which the root cannot be grasped with ordinary forceps, and for which the Sapien Root Remover System is therefore indicated as the method of choice for root extraction. A typical procedure using the System will cause less tissue trauma than other surgical alternatives, and will provide an osteotomy site ready for immediate implant placement.



## PRECAUTIONS, ASSISTANCE AND DISCLAIMER

We welcome and respond to requests for technical assistance from users of the Sapien Root Remover System. Read these Instructions and view the instructional and clinical videos (found on either <http://www.SapienRD.com> or the instructional CD) before using the System. Whether or not you have already watched the clinical videos, we recommend that you watch them again after reading these Instructions. You will have a better comprehension of what you see in the videos after reading these Instructions.

The components that comprise the Sapien Root Remover System are designed to be used together. Except for the Manual Driver, they are not intended for use with other devices or for use apart from the System. The Manual Driver may be used in place of a power-driven latch head hand piece in any situation where fine manual control is required, for example, in driving abutment screws of dental implants or in screwing a dental implant in difficult to reach areas. By placing an order for replacement parts, you are affirming that you own the Sapien Root Remover System and that you will use the replacement parts only in connection with the System.

Use the Sapien Root Remover System only to extract tooth roots in accordance with these Instructions. Do not use the System if you are not a professionally trained dental care provider. The System has been designed to accomplish atraumatic root extractions that are minimally invasive for the large majority of cases. Surgical extraction does, however, involve inherent risk to surrounding tissues, and the dental practitioner must make a clinical decision balancing the risk from injury to surrounding tissues against the risk of leaving a broken root in the jaw, or against the risk presented by alternative root extraction methods.

If you have questions about how to use the Sapien Root Remover System, or have difficulty using the System, we encourage you to contact Dr. Sapien by e-mail at [SchubertSapien@sapienrd.com](mailto:SchubertSapien@sapienrd.com), or by telephone at (817) 886-0365.

We disclaim liability for use of the System by anyone who has not first carefully studied the written and visual instructional materials, or for use of the System in a manner that is improper or inconsistent with these Instructions.

# SAPIAN ROOT REMOVER SYSTEM COMPONENTS

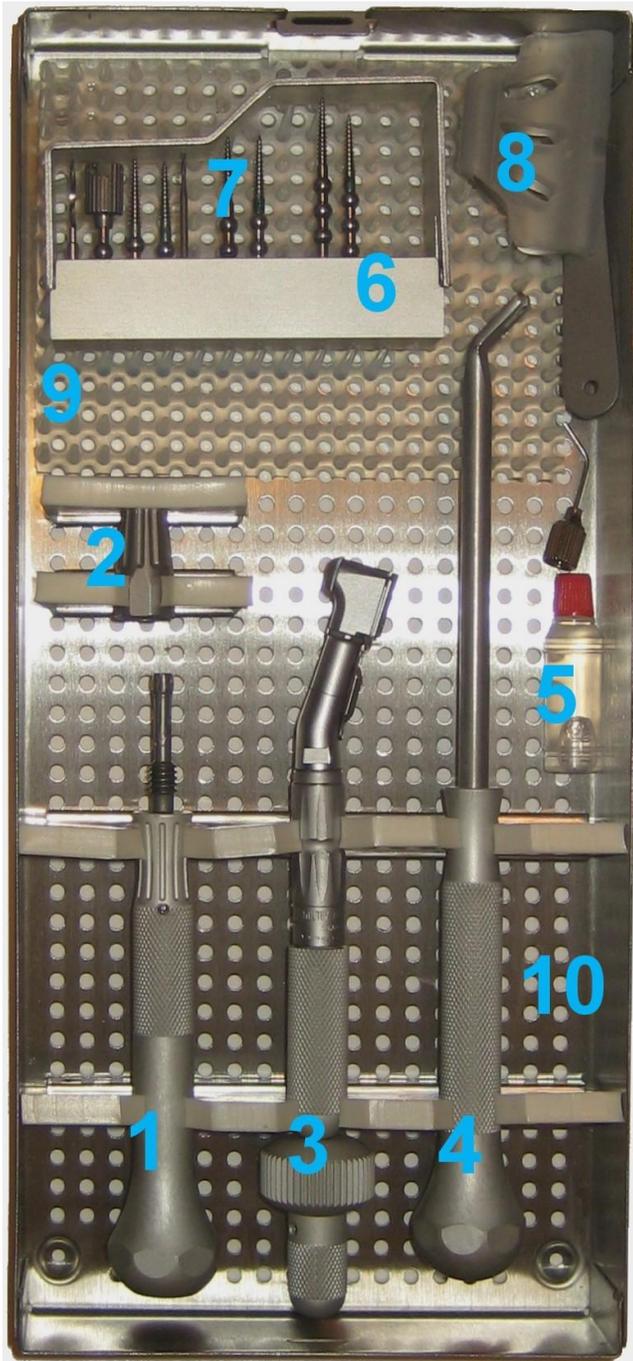


Figure 1. Sapien Root Remover System labeled components.

1. Anterior driver
2. Collet nut for anterior driver
3. Manual latch head driver
4. Pry Bar
5. Gear oil vial and spout for manual latch head driver
6. Extraction Screw block with built-in screw straightener
7. Aluminum screw block containing:
  - a. Three thin Extraction Screws: one 1-ball, one 2-ball and one 3-ball.
  - b. Three thick Extraction Screws: one 1-ball, one 2-ball and one 3-ball.
  - c. Finger Driver
  - d. # 557 Surgical high speed cutting bur
  - e. 35.5 mm total length RA tapered pilot drill
  - f. 41mm total length RA tapered pilot drill
8. Fulcrum Tray with removable Silicone Elastomer Cushion pad
9. Soft silicone pin mat cushion for screw block and Fulcrum Tray
10. Autoclavable stainless steel sterilization cassette

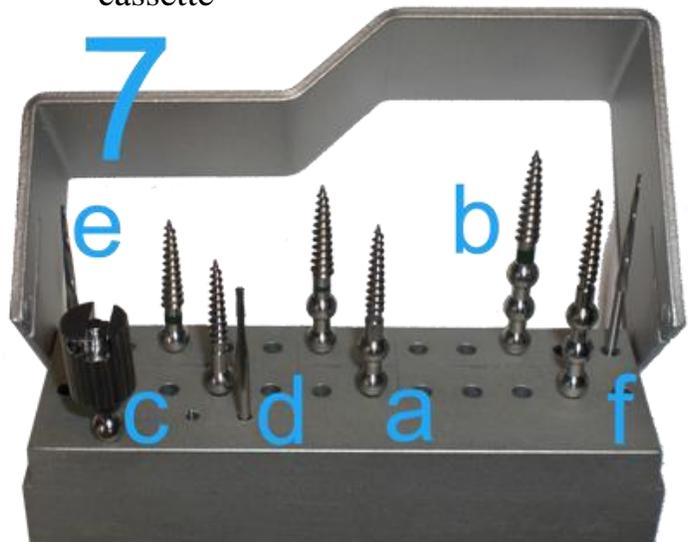


Figure 2. Screw Block labeled components.

## INSTRUCTIONS FOR USE

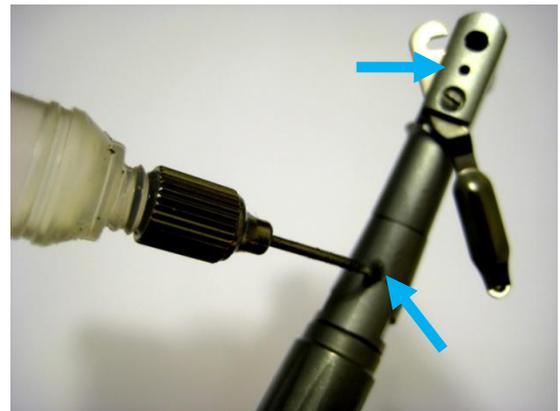
*Root extraction with the Sapien Root Remover System typically requires 1-5 minutes. A few more minutes may be required to extract a multi-rooted tooth that requires sectioning. You can view a multi-rooted tooth extraction in the Example Cases section and in the clinical videos. As shown, a multi-rooted tooth can sometimes be removed without sectioning if the tooth is properly mobilized before the extraction.*

### **Overview of Directions**

- Step 1: Ensure sterilization of instruments
- Step 2: Cut or break periodontal ligaments and luxate root
- Step 3: Prepare a pilot hole for Extraction Screw
- Step 4: Select proper Extraction Screw
- Step 5: Choose driver and place Extraction Screw
- Step 6: Position Fulcrum Tray to support Pry Bar
- Step 7: Position Pry Bar, open wide, and extract
- Step 8: Remove extracted root from Extraction Screw
- Step 9: Sterilize and store Sapien Root Remover System for next use

### **Step 1: Ensure sterilization of instruments**

Sterilize the Sapien Root Remover System components prior to each use. You may sterilize the entire System with components in place in the self-contained sterilization cassette tray. Lubricate the manual driver hand piece with oil before sterilization. (Remove the vial of lubricating oil before sterilization.) We recommend steam autoclaving. Chemical vapor or ethylene oxide sterilization is also acceptable. We do not recommend dry heat sterilization because it destroys the soft silicone parts inside the instruments and in the sterilization tray. Do not expose the Sapien Root Remover System to temperatures above 300 degrees Fahrenheit.



**Figure 3. Use oil included with the System to lubricate the Manual Driver before sterilization.**

An autoclave temperature and time pressure chart can be found at:

<http://www.sterilizers.com/autoclave-time-temperature-pressure-chart.html>

## Step 2: Cut or break periodontal ligaments and luxate root

Cut or break the PDL and mobilize the root to facilitate the extraction. If the root is not already mobile, loosen the root by driving a periotome mesially/distally between the bone and the root (**Fig. 4(a)**). If necessary, use elevators to luxate the root (**Fig. 4(b) and 4(c)**). These steps will reduce periodontal ligament attachments and decrease force needed to extract the root.



Figure 4. Cut PDL with a periotome (a). Use elevators to luxate root (b, c).

## Step 3: Prepare pilot hole for Extraction Screw



Prepare a pilot hole in the root to facilitate proper engagement of the Extraction Screw in the root, and to reduce the likelihood that the root will split from the stress of extraction (**Fig. 5**). Use either a #557 surgical bur with a high speed hand piece or a tapered pilot drill with a slow speed latch hand piece (three pilot drills are included in the System, **Fig. 2**). Drill to a depth of at least 4-6 mm in a longitudinal direction with the root.



For cutting through highly calcified teeth, the slow speed pilot drills may not be effective, and the high-speed # 557 surgical bur may be required. Where a root canal is large or already apparent, the self-tapping threads of the screw may engage in the canal without prior drilling of a pilot hole.

Figure 5. Preparing pilot hole using slow speed pilot drill (a), and high speed # 557 surgical bur (b).

It is not common for a tooth to split during extraction. However, some roots are so decayed that they will split from the extraction force stress. If the root disintegrates during extraction, retrieve the root fragments using root-tip picks, and if possible, remove all residual root material with high evacuation suction.

#### Step 4: Select proper Extraction Screw

Sapian Root Remover Extraction Screws have thin or thick tapered threads, and one, two or three lift balls on the shaft post. For easy identification, the thick screws are marked by a dark band around the shaft (**Fig. 8**).

#### Choice of one, two or three ball Extraction Screw

Choice of a one, two, or three ball Extraction Screw will depend on the depth of the root and the clearance within the mouth. When the screw is in the tooth and ready for extraction, the lifting ball on the screw shaft should be 3-4 mm above the occlusal level of the adjacent teeth (**Fig. 7**). The proper choice for the Extraction Screw can be determined by comparing the Extraction Screw against the radiograph (**Fig. 6**). The shorter one-ball screw shaft will ordinarily be easier to use on posterior extraction sites with limited vertical space, but can be used in any location where the ball rises the proper distance above the occlusal surface. The two or three-ball screws are longer and allow for greater flexibility in positioning the screw so that the ball is at the appropriate level for creating extraction leverage. They can be used in any location with sufficient vertical clearance to accommodate their length.

#### Choice of thin or thick Extraction Screw

Extraction Screws come with either thick or thin thread tapers. To permit easy recognition of thin and thick screws, thick screws are marked by a dark band. A thin screw is preferred for situations where the extraction angle or other circumstances necessitate the use a more flexible screw. A thick screw is useful where greater rigidity provides a structural advantage in the extraction mechanics. Some roots will be so severely decayed that the threads of a thin Extraction Screw will not engage firmly in the root. In this case, the thick Extraction Screw will usually have sufficient grasp to remove the root.



**Figure 6. Compare Extraction Screw to radiograph to select proper Screw.**



**Figure 7. Lift ball on screw shaft about 3-4mm above occlusal plane.**



**Figure 8. For ease in differentiating thin and thick Extraction Screws, thick screws have a dark band, as shown above.**

## Step 5: Choose driver and place Extraction Screw

As determined by your own preference and convenience, select either the Anterior Driver or the Manual Latch Head Driver for Extraction Screw placement. Detailed instructions for each appear below. Use the Anterior Driver for convenient screw placement in anterior and premolar maxillary teeth. This driver can be used with one hand to place the Extraction Screw with precision, speed and maximum tactile sensitivity. Alternatively, use the Manual Latch Head Driver to place an Extraction Screw in any part of the mouth, including areas that cannot be reached with the Anterior Driver. Operating the Manual Driver requires two hands.

### Anterior Driver



Figure 9. Labeled parts of the Anterior Driver

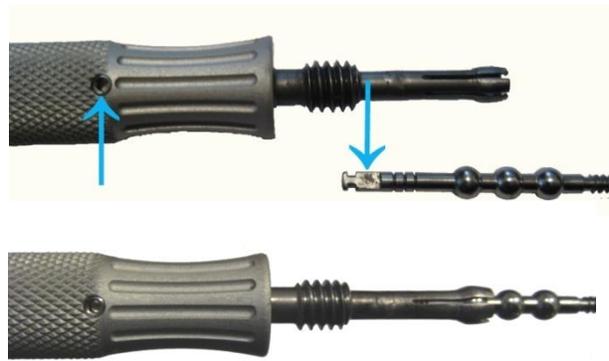
1. The Anterior Driver is designed to efficiently place Extraction Screws in upper anterior roots (**Fig. 10**) and can be conveniently used to remove Extraction Screws from extracted roots. The Anterior Driver can be used with one hand, much like a screwdriver (see “Sapian Root Remover 3” video at [www.SapianRD.com](http://www.SapianRD.com)).

2. Remove the collet nut and insert the post of the Extraction Screw into the collet so that the screw threads point away from the Anterior Driver and the flat of the screw post is aligned with the small set-screw hole on the handle of the Anterior Driver (**Fig. 11**). Firmly push the Extraction Screw until the ball on the screw post engages inside the curved collet splines. The screw shaft should click into place as the Extraction Screw ball engages. This locks the Extraction Screw in place while it is being screwed into the root. Place the collet nut over the Extraction Screw and rotate it clockwise to engage its threads. Turn the collet nut until it is snug. Do not over tighten. You will unscrew this nut with your fingers to disengage the Extraction Screw after the Screw is placed.



Figure 10. The Anterior Driver is designed to place Extraction Screws in upper anterior roots.

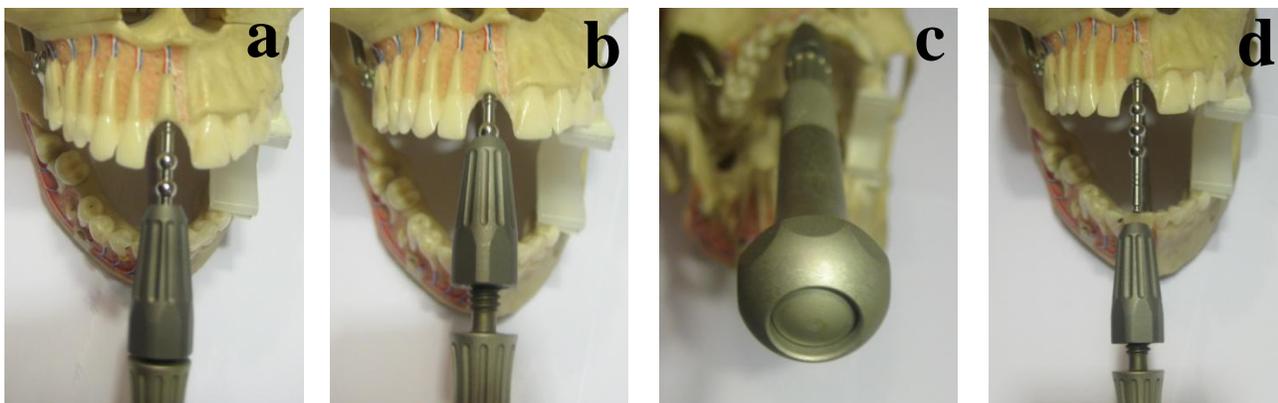
3. Once you understand how the Extraction Screw is inserted into the Anterior Driver it is unnecessary to completely remove the collet nut when inserting or removing Screws. Simply loosen the nut 3-4 turns to create a 5-7 mm space between the nut and the handle (or until threads begin to show), then insert the Extraction Screw so that the flat section at the top of the screw shaft aligns with the set-screw hole on the handle. The screw shaft will click into place as the Extraction Screw ball engages into the curved collet basket.



**Figure 11.** Align the flat on the Screw post with the set screw on the Anterior Driver handle

4. Like using a screwdriver, carefully insert the Extraction Screw tip into the pilot hole or root canal with engaging apical pressure, then rotate the Anterior Driver until the Extraction Screw is snug. The screw should be engaged at least 3-4 thread lengths or more into the root to ensure that the screw is securely placed. Do not force the Extraction Screw too tightly into the root.

5. Confirm that the Extraction Screw is placed into the root as intended. If you have any doubt regarding the placement, confirm with a periapical radiograph. Once you are assured that the Extraction Screw is securely placed, disengage the Anterior Driver from the screw by holding the handle of the Anterior Driver with one hand while using the other hand to loosen the collet nut 3-4 turns counter-clockwise. Then, push the release button at the end of the handle to disengage the screw and withdraw the Anterior Driver (**Fig. 12**).



**Figure 12.** After the Extraction Screw is securely placed (a), disengage the Anterior Driver. Loosen the collet nut 3-4 turns (b), push the release button (c), and withdraw the Driver (d).

## Manual Latch Head Driver

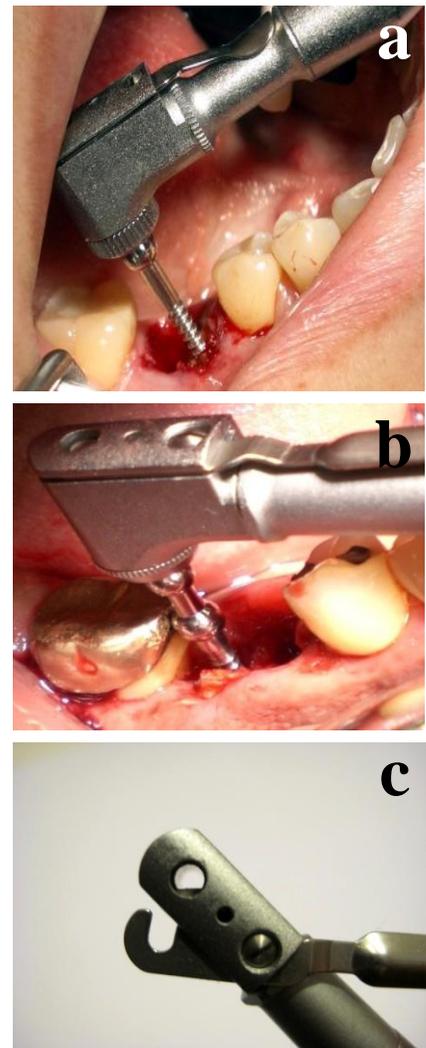


1. The Manual Latch Head Driver is designed to place Extraction Screws in hard to reach places such as posterior roots. As shown in the clinical demonstration videos, using the Manual Latch Head Driver requires two hands.

2. Open the retention latch by sliding it to the right. Insert the Extraction Screw into the Manual Latch Head Driver by aligning the flat of the screw shaft with the flat in the driver and secure it by sliding the latch closed (**Fig. 13(c)**). Test the screw's retention in the driver before inserting into the mouth. Until you get the feel of securely positioning the Extraction Screw in the latch head, you may find it necessary to give careful attention to adjust the insertion in order to achieve a secure fit. With a few practice trials, you will accomplish this easily.

3. Carefully insert the Extraction Screw tip into the pilot hole or root canal with engaging apical pressure. Rotate the knob on the Manual Latch Head Driver clockwise with one hand until the Extraction Screw is snug. Rotation may be performed using either the small knob at the end of the driver, or using the larger knurled knob. Use your other hand (thumb and forefinger) to hold the latch head and apply apical pressure. The screw should be engaged at least 3-4 thread lengths into the root to ensure that the screw is securely placed. You will feel the Extraction Screw tighten as you turn the driver. Do not force the extraction screw to tightly into the root.

4. Confirm that the Extraction Screw is placed into the root as intended. If you have any doubt regarding the placement, confirm with a periapical radiograph. Once you are assured that the Extraction Screw is securely placed, release the screw by sliding the latch open on the driver head and remove the screw.



**Figure 13.** The Manual Driver is ideal for screw placement in posterior roots (a, b). A close up view of the head of the Manual Driver with the retention latch open (c).

NOTE: The Extraction Screw should be inserted only until it is snug. Exercise care to avoid splitting the root or driving the screw into bone or other vital structures. Although it is not common for a tooth to split during extraction, in rare instances roots are so decayed that they will split from the stress of inserting the Extraction Screw or of the extraction itself. When placing an Extraction Screw without a pilot hole, there is increased risk of a split root. If a root does disintegrate during the procedure, retrieve the root fragments using root-tip picks, and if possible use high evacuation suction to remove all residual root material.

### Finger Driver

The Finger Driver slips easily onto the non-threaded end of an Extraction Screw (**Fig. 14**). (Note that when an Extraction Screw is inserted into the Anterior Driver or the Manual Driver, the flat portion of the Extraction Screw shaft must be aligned with a keyway inside the driver.)

The Finger Driver has three uses. First, it can be used after completing a root extraction to provide a quick, convenient way to remove the screw from the extracted root. This use is described on Page 15, under the section heading “**Step 8: Remove extracted root from Extraction Screw**”. A second use for the Finger Driver arises when the location of a tooth or reduced vertical clearance makes it difficult to place an Extraction Screw using other drivers. In such cases, the Finger Driver can be used to place the Extraction Screw anywhere you can reach using your fingers to twist and insert the screw. When using the Finger Driver in the mouth, insert at least two feet (60 cm) of floss through the hole provided to ensure easy retrieval if the Finger Driver is accidentally dropped or swallowed. Third, use the Finger Driver to straighten bent Extraction Screws as discussed under “**Straightening bent screws**” on Page 16 of these Instructions.



**Figure 14.** The Finger Driver slips easily onto the non-threaded end of an Extraction Screw



**Figure 15.** Quick-set registration material can be used to protect delicate structures.

## Step 6: Position Fulcrum Tray to support Pry Bar

The Fulcrum Tray supports the downward force of the Pry Bar and protects delicate structures. The downward force on the handle of the Pry Bar creates the vertical force that lifts the Extraction Screw. The Fulcrum Tray must be positioned to provide maximum support for such downward pressure.

Proper positioning of the Fulcrum Tray is critical to the success of the extraction. Review these instructions carefully to understand and develop this skill.

Sometimes the best support for the Pry Bar comes from positioning the Fulcrum Tray directly over the Extraction Screw, with the Extraction Screw shaft extending through one of the openings in the Fulcrum Tray (**Fig. 16(a), 17 (a)**). There are also times, such as with posterior molars, when the best support comes from positioning one end the Fulcrum Tray adjacent to the Extraction Screw (**Fig. 18**). When there is limited space or visibility, you may find it easiest to first position the Pry Bar cradle under the lift ball of the Extraction Screw, then slide the Fulcrum Tray under the Pry Bar (**Fig. 20**). As shown in the photos, when the Fulcrum Tray is positioned alongside the Extraction Screw, the screw will not protrude through one of the holes in the Fulcrum Tray.

When the Fulcrum Tray is properly positioned, the prongs of the Pry Bar will fit snugly between the support surface of the Fulcrum Tray and the lifting ball on the Extraction Screw. As a general rule, this requires about 3-4 mm. of space between the lift ball and the occlusal surface of teeth adjacent to the extraction site. The space between the Fulcrum Tray support surface and the lifting ball can be modified by skillfully positioning the Fulcrum Tray. For example, as noted above, if there is not sufficient room to place the entire Fulcrum Tray and the Pry Bar under the lifting ball without repositioning the screw, it is often possible to first place the Pry Bar prongs in position under the lift ball, and then



**Figure 16. (a) Pry Bar and Fulcrum Tray properly aligned in mesial-distal direction. (b) DO NOT exert extraction force when the Pry Bar and Fulcrum Tray are not aligned parallel to the mesial-distal direction. This error creates risk of fracturing the buccal plate.**

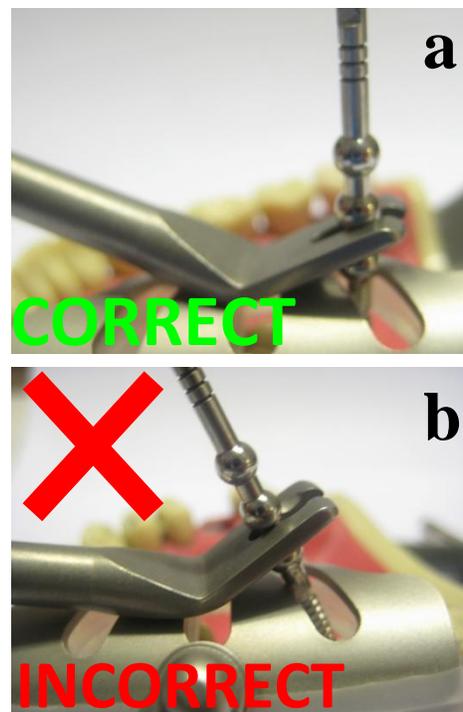
slide one end of the Fulcrum Tray under the Pry Bar to provide a leverage support surface (**Fig. 18, 20**). Or, if there is too much space between the Pry Bar prongs and lift ball, you can make a temporary shim to fill the space by placing another available object, such as the handle of your mirror, to fill the space between support surface of the Fulcrum Tray and the Pry Bar fulcrum.

Exercise care to avoid damage to surrounding structures when positioning and exerting force on the Fulcrum Tray. If adjacent teeth are extremely loose, or surrounding tissue is vulnerable to pressure, you may provide additional support and protection for surrounding structures that will come in contact with the Fulcrum Tray by using a quick-set hard body impression material (e.g., quick set registration polyvinyl-siloxane material such as bite registration material) between the Fulcrum Tray/Silicone Pad and the surrounding tissue (**Fig. 15**).

### **Step 7: Position Pry Bar, open wide, and extract**

If you look closely between the prongs of the Pry Bar, you will see a “cradle” shaped to fit the Extraction Screw ball. Slide the Pry Bar prongs under the Extraction Screw ball until the ball sits within this cradle (**Fig 17(a)**). Extraction force must be applied in a vertical direction aligned with the root. Prying the screw when the ball is NOT in the cradle will cause the screw to bend, rather than lift. (**Fig. 17(b)**). **DO NOT attempt to pry the screw if the ball is not in the cradle.** Provide stable support for the Fulcrum Tray and Silicon Cushion Pad. When adjacent teeth are missing or compromised, take precautions to protect the existing structure. Supplemental support and protection can be provided by building a stable base for the Fulcrum Tray with polyvinyl-siloxane (see further discussion under **Step 6: Position Fulcrum Tray to support Pry Bar**).

Align the Pry Bar in a mesial-distal direction to prevent damage to the buccal plate and maximize extraction force (**Fig 16, 19**). The fulcrum of the Pry Bar on the Fulcrum Tray should be directly over the strongest adjacent tooth, which is usually mesial of the root to be extracted.



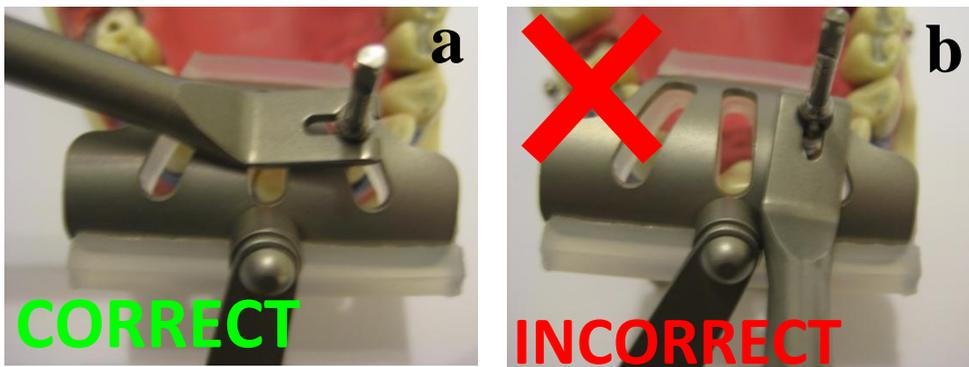
**Figure 17. (a) Correct positioning of lift ball in Pry Bar cradle, ready for extraction. (b) Incorrect positioning – lift ball is NOT in Pry Bar cradle. Application of extraction force in this position will result in a bent screw.**

Have the patient open wide and/or move the mandible to one side to allow room to extract the root without damaging the opposing dentition. Use gentle but firm pumping pressure to push down on the Pry Bar lever and lift the root from the socket.

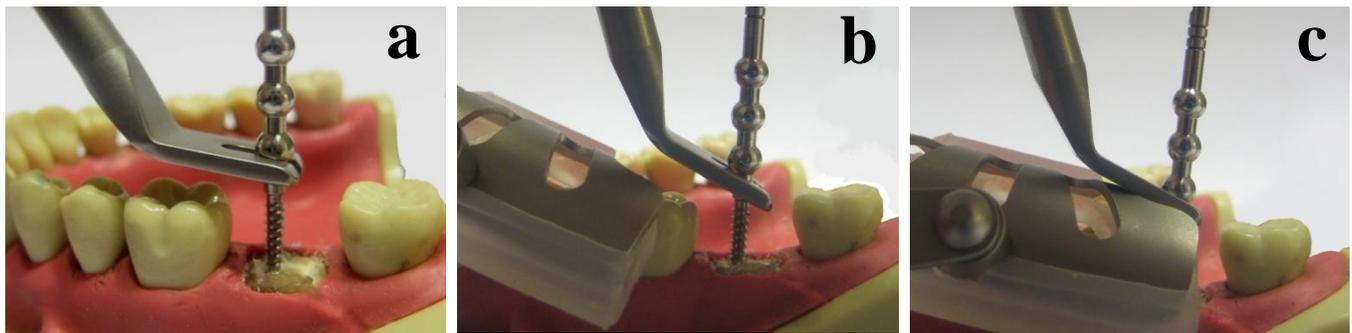
In cases where the roots are long and difficult to remove, exerting firm pressure for approximately 2 seconds and then releasing or relaxing the force on the Pry Bar allows fluid or blood to enter the PDL space, facilitating the extraction. Be patient, wait a moment, then reapply controlled force. To protect other oral structures, guide the Extraction Screw with your hand/fingers as it moves vertically. The typical result will be preservation of bone and a clean osteotomy site ready for immediate implant placement (**Fig. 21**).



**Figure 18. Proper placement of the Extraction Screw, Fulcrum Tray, and Pry Bar.**



**Figure 19. (a) Pry Bar and Fulcrum Tray properly aligned in mesial-distal direction for anterior extraction. (b) Pry Bar NOT properly aligned with Pry Bar in a mesial-distal direction. DO NOT exert extraction force in this position. This error creates risk of fracturing buccal plate.**



**Figure 20. When space and visibility are limited, it may be more practical to place Pry Bar in position (a), then slide Fulcrum Tray under Pry Bar (b, c).**

### **Step 8: Remove extracted root from Extraction Screw**

The extracted root can be removed from the Extraction Screw by using the Finger Driver, the Anterior Driver or the Manual Driver. The Finger Driver is usually the quickest and easiest for this task. Simply hold the root firmly with one hand, preferably with a 2" square gauze pad, and unwind the Extraction Screw with the other hand until the root is released (**Fig. 22**). Exercise care to avoid bending the screw while removing the root. If the Extraction Screw is bent during the extraction process, follow the procedure on Page 16 for straightening bent screws.

### **Step 9: Sterilize and store Sapien Root Remover System**

The Sapien Root Remover Kit should be sterilized after use and stored in a sterile environment in preparation for its next use. For additional notes on sterilization, refer to **Step 1: Ensure sterilization of instruments**, on Page 5 of the Instructions.



**Figure 21. Clean osteotomy site.**



**Figure 22. Remove Extraction Screw from root.**

# EXTRACTION SCREWS: DESIGN, PERFORMANCE, REUSE

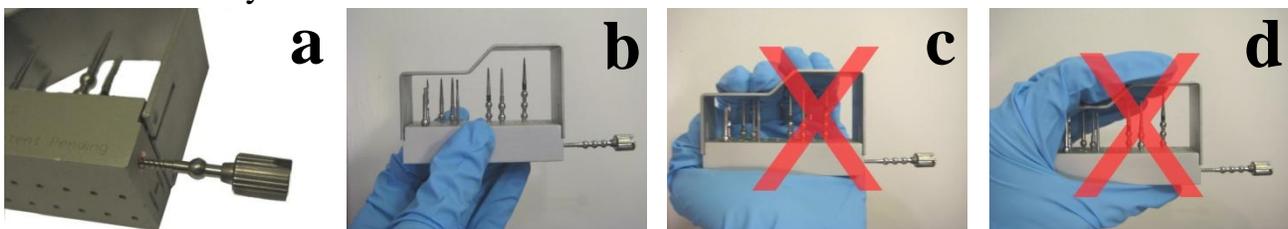
## Reusing Extraction Screws, bending and breaking

Our Extraction Screws are manufactured with high grade stainless steel, and the thread pattern is engineered for durable cutting and gripping. The screw is a replaceable part whose life will vary depending on the stress placed upon it during extraction. Under ideal conditions screws can be re-used a number of times. The Screws are designed to bend under extreme stress before breaking. The Extraction Screw may bend or break when a root has not been luxated or mobilized prior to extraction, or under unusually extreme extraction conditions. Bent screws can often be straightened and re-used as described below.

Generally, the Extraction Screw should not be used to create a back and forth motion to luxate the tooth root. However, the dentist may decide that the procedural advantage of such action justifies the risk of breaking or damaging the screw. If a screw does break, a second screw can usually be placed to complete the procedure. If a new screw cannot be placed, an alternative extraction method (e.g. periotomes) will be necessary.

## Straightening bent Extraction Screws

A Screw with a moderate bend can often be straightened and reused. As shown in **Figure 23(a)**, use the Finger Driver (see **Finger Driver**, Page 11) to hold the bent Screw while inserting the thread tip into the hole on the side of the Screw Block. Grasp the Screw Block securely (**Fig. 23(b)**) and apply pressure to remove the bend from the Screw. Do not hold the lid while attempting to straighten a screw (**Fig. 23(c) and 23(d)**); the lid can swing open, leading to injury from sharp points inside. Severely bent Screws may not yield to straightening, but most screws can be straightened several times before their use cycle is exhausted.



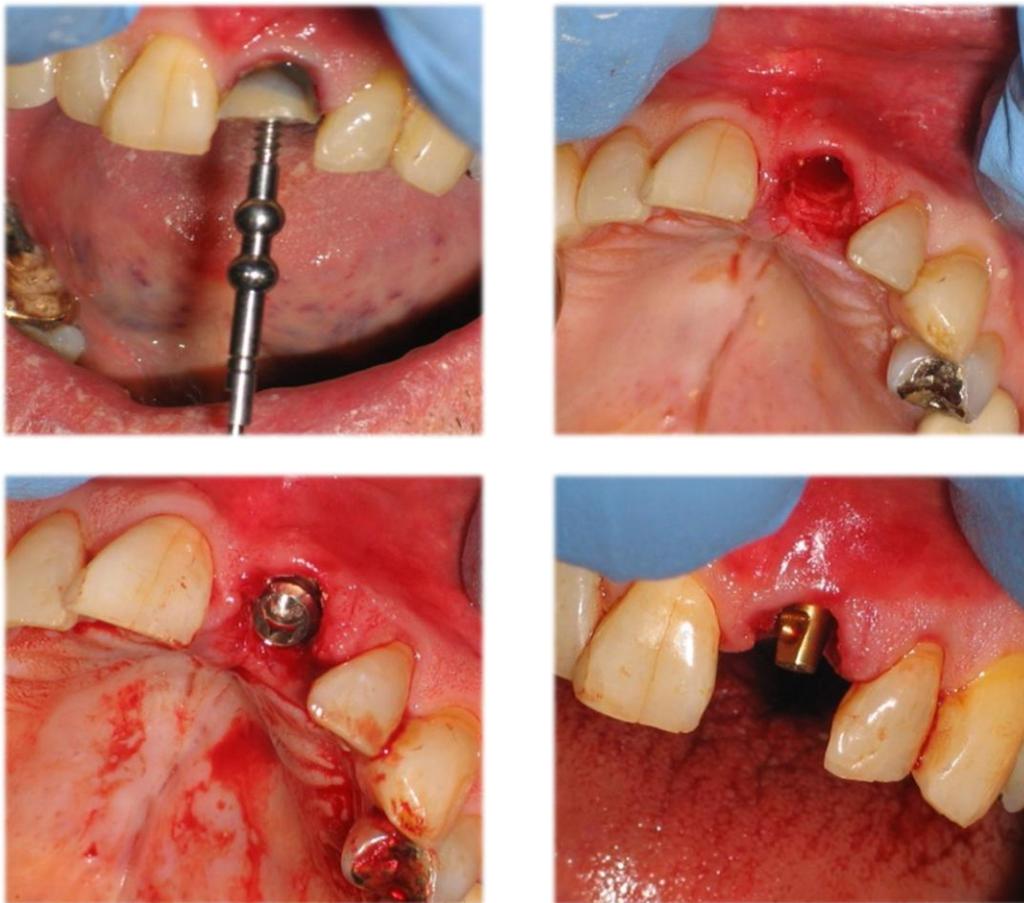
**Figure 23.** Using screw straightener, proper grasp of screw block (a, b). Do not grasp the lid of the Screw Block while straightening a screw (c, d).

## EXAMPLE CASES

(For additional example cases, see the clinical videos on your instructional CD or at <http://www.sapianrd.com>)

### **IMMEDIATE IMPLANT**

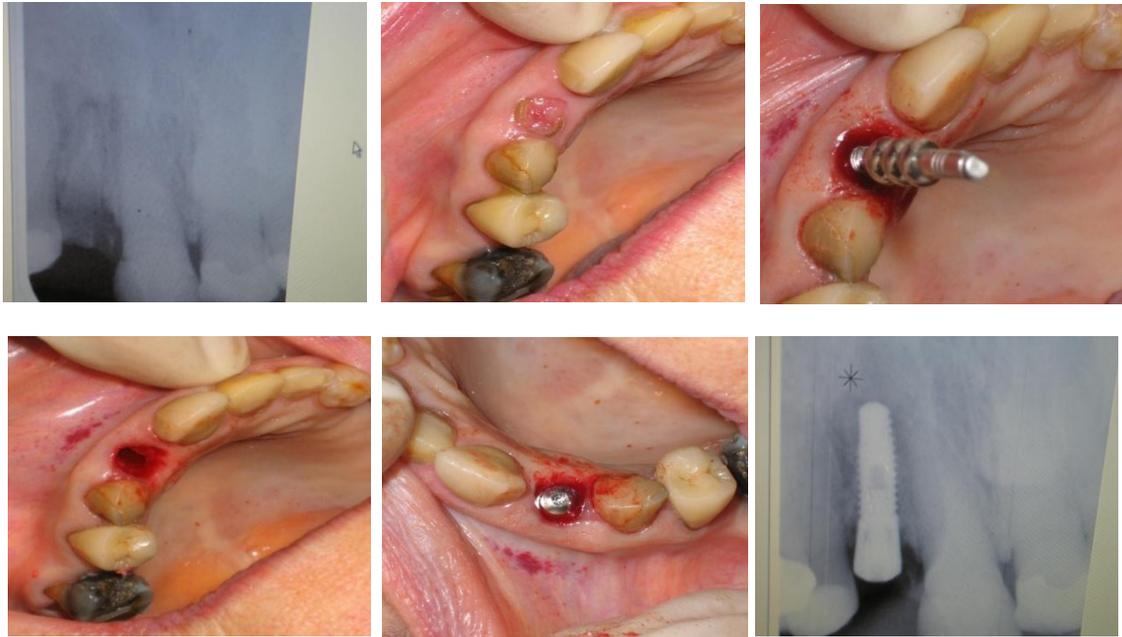
As illustrated below, root extraction with the Sapien Root Remover System minimizes damage to hard and soft tissue and leaves the extraction site ready for immediate implant placement.



*Photos courtesy of Dr. Matthew Rudolph, periodontist.*

## IMMEDIATE IMPLANT

As illustrated below, root extraction with the Sapien Root Remover System minimizes damage to hard and soft tissue and leaves the extraction site ready for immediate implant placement.



*Photos courtesy of Dr. Matthew Rudolph, periodontist.*

## MOLAR ROOT EXTRACTIONS

In the case illustrated below, the Extraction Screw was inserted in the largest canal, i.e., the palatal canal. After the tooth was luxated and the periodontal ligaments were severed, the entire tooth was extracted without the necessity of sectioning individual roots. The more common approach, when the size of the roots permits, is to cut the PDL and luxate the roots, then section the roots using a # 557 surgical bur. A pilot hole is created in each separate root, and each root can then be individually extracted.



*#14 Root has no purchase points. Forcep extraction is not possible in this case.*



*Polyvinyl Siloxane material can be used to protect surrounding structures and provide additional support during extraction.*



*Severe tooth decay precludes extraction with forceps*



*Divergent multi-root extraction performed without sectioning roots.*

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For questions or technical assistance please contact

[SchubertSapian@SapianRD.com](mailto:SchubertSapian@SapianRD.com)