

Gray Market FAQ

Patterson Dental

1. What is the dental “gray market”

According to the U.S. Food and Drug Administration, the term “gray market” generally refers to products that are sold outside the established distribution chain, typically at a deeply discounted price (e.g., products intended to be sold abroad, but instead imported and sold in the U.S.). Such products may – or may not – satisfy FDA-related requirements, or other applicable laws and regulations.

2. Are gray market products illegal?

Gray market products are not by definition illegal. However, if these products were intended for foreign markets, they likely will not satisfy United States specific FDA-related requirements. Because products available on the gray market may be indistinguishable from defective or counterfeit “black market” products that travel through those same distribution channels, it may be difficult to tell whether the product is legally able to be sold in the United States. Such products may have been diverted from planned destruction or even have been recalled.

3. If it’s not always illegal, why are gray market products bad?

Customers cannot be confident that products purchased through the gray market are genuine or safe or that they have been handled appropriately. By purchasing gray market products, dentists expose themselves and their patients to unnecessary risk, uncertainty and potential liability from defective items.

4. Is dental counterfeiting growing?

Unlike gray market products, counterfeit products are absolutely illegal. Unfortunately, it is becoming easier and easier for counterfeiters to replicate packaging of legitimate products. By offering deeply discounted products, counterfeiters take advantage of unsuspecting purchasers to compete on price to gain market share.

5. How do gray market products find their way into dentists’ offices?

Gray market products typically have a significantly lower price point than legitimate products. Because buyers tend to appreciate value and “deals,” dental supplies may be ordered by individuals unaware that a gray market even exists in the dental arena. Typically, discount ranges of at least 10 percent are available from gray market dental supply discounters.

6. What can a dentist do to ensure no gray market products are used in their practice?

Dentists should only order from authorized distributors of their supply needs to ensure that their purchases are authorized, legitimate and warranted. Major product manufacturers will have lists of authorized distributors readily available for review.

If you have a question about the legitimacy of a discounting distributor, do not hesitate to contact the manufacturer directly. Purchasing from the major U.S. distributors, such as Patterson Dental, helps ensure the integrity of the supply chain.

7. How can a dentist identify gray market products?

Although these products may be difficult to identify, there are several proactive methods you can use to identify what may be a gray market or even counterfeit dental supply:

Low price. The product is selling for significantly below the known market price. You may research a product's market price by reviewing major dental retailer's online or printed catalogs.

Unknown distributor. If the company selling the product does not have a readily recognizable name, be suspicious. In today's information age, it is very easy to research legitimate distributors and businesses. All major manufacturers will have lists of their authorized distributors available for you to use.

Suspicious packaging. Thoroughly examine the printing on all packages. If the package is unclear, smeared, irregular, uneven or not of the same quality you have previously observed on packaging of products with the same brand name, it may be from the gray market. Other packaging issues may include old product names, passed expiration dates, lack of a bar code, omitted disclaimers or other mandated regulatory verbiage. Be sure the label on the product matches the product name on the directions for use.

8. With the proliferation of the Internet and online purchasing is there even more opportunity for these products to make their way into the marketplace?

Yes. It is likely that growth in the gray market in recent years may be attributable to online businesses.

9. What is Patterson doing to deal with the gray market concerns?

Patterson Dental is taking an industry leadership position to help ensure the integrity of the dental supply chain and protect against potentially unsafe dental products entering the marketplace. In addition to raising industry awareness, we are formalizing our efforts to assure that products distributed through Patterson Dental are sourced directly from the product's manufacturer.

10. Why is Patterson taking a public stance on this issue?

Patterson Dental has worked hard for years to ensure the highest integrity of our supply chain, and we hope that the rest of the dental supply industry will show a similar commitment to secure their own supply chains. We are very concerned about the potential problems that could result if this issue isn't properly addressed. Our customers' reputations and their patients' safety continue to be one of our highest priorities.

11. What does Patterson Dental hope to accomplish through its leadership in this issue?

We hope to educate our customers. The consequences from using a product not intended for our market could be significant. For example, imagine a composite failing because it was made of material not approved for the United States market. We want to help protect our dental customers and their patients from products that may be potentially unsafe.

12. Is anyone else in the dental industry concerned about the gray market?

To date, the efforts on supply chain integrity have been led by product manufacturers. This has occurred through sophisticated packaging, the installation of unique product coding systems, including RFID technology

13. What actions do you want others in the dental industry to take?

We have worked hard to ensure the highest integrity of our supply chain and we hope that the rest of the dental supply industry, particularly the distributors, will show a similar commitment. We do not believe that this is only an issue for regulators or manufacturers. Distributors also must take ownership of the issue, to ensure the security of their respective supply chains.

14. What steps is Patterson taking to educate the marketplace?

Patterson Dental is launching a broad awareness campaign at www.DentalSupplyIntegrity.com to help educate dentists and their patients. In addition, we hope to work more closely with the dental industry to develop safeguards and protections. We take our commitment to this issue seriously.