



Use and care instructions for your  
**Invisalign® Palatal Expander System**



ENGLISH .....2

# English

## Read these instructions before use

Before using the Invisalign Palatal Expander System, patients (and, for minor patients, their parent(s) or legal guardian(s)) should carefully read these instructions for important information about expander and holder wear. These instructions include warnings and precautions, guidance on proper care of the devices, and important recommendations on maintaining oral hygiene during treatment. Parents and legal guardians should ensure that any other adult who is responsible for helping the patient with the device or for monitoring the patient's use of the device also reads and understands these instructions.

We recommend that you save these instructions for future reference. If you have questions or concerns, please contact your doctor .

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## THE INVISALIGN PALATAL EXPANDER SYSTEM

The Invisalign Palatal Expander System consists of doctor-prescribed, additive-manufactured (3D printed) removable orthodontic devices (Invisalign Palatal Expanders and Invisalign Palatal Holders), 3D software, and Invisalign Attachment Templates. These orthodontic devices are used to expand and subsequently hold patients' narrow maxilla (upper jaw, dental arch and teeth, palate) with primary (baby or milk), mixed (primary and permanent), or permanent teeth until the doctor begin the next phase of treatment. Small 'attachments' will be bonded to your teeth during the beginning of your treatment; these attachments help to hold the device in place. The expanders and holders are made from polyamide-12, a polymer also known as nylon 12, a type of nylon.

### Expansion Phase

Invisalign Palatal Expanders are staged to expand your palate in small increments to a final position chosen by your doctor. Each expander is intended to be worn day and night; you should comply with your doctor's instructions on wear time. Expanders are intended to be replaced daily for rapid expansion or changed less frequently for slow expansion, at your doctor's discretion.

Each expander in the series is referred to as a 'stage'. The first stage (stage 0) of the expander series is used to help you get used to the device and for potential optimization of the attachment bond. Small attachments will be bonded to your teeth at the beginning of your treatment; these attachments help to hold the device in place and aid with expansion. After stage 0, each stage is programmed for active expansion of your palate. Your doctor will decide when to stop the expansion phase and may do so before you have used all of your expander stages.

### Holding Phase

The Invisalign Palatal Holder is a copy of the last stage of the expansion phase (chosen by your doctor) and is designed to hold your expanded palate throughout the 'holding' phase before you progress to the next phase of your treatment. Unlike the expanders, the holders are 'passive' (not programmed for active palatal expansion) and remain the same throughout the holding period. Each holder should be worn day and night for a minimum of 2 weeks and a maximum of 4 weeks (at your doctor's discretion) before replacement with a new (duplicate) holder or progression to the next phase of treatment. The number of holders provided will depend on the duration of holding phase determined by your doctor.

If your doctor submits new scans for additional expansion or before the holding phase, new attachments will be bonded to your teeth.

## INDICATIONS FOR USE

The Invisalign Palatal Expander System is indicated for the orthodontic treatment of malocclusion. The system is used for rapid expansion and subsequent holding of skeletal and/or dental narrow maxilla (upper jaw, dental arch and teeth, palate) with primary, mixed, or permanent dentition during orthodontic or orthopedic treatment in children or adolescents. In adults, it is to be used in conjunction with surgery or other interventions when necessary.

## WHEN THE DEVICE SHOULD NOT BE USED (CONTRAINDICATIONS)

The Invisalign Palatal Expander System is contraindicated for use in patients with the following conditions:

- Active periodontal disease\*
- Active caries (tooth decay or cavities)
- Hereditary angioedema (HAE)

\*If you have periodontal disease that is treated, controlled or arrested (not 'active'), your doctor may still treat you with this device.

## WARNINGS

**Note:** For minor patients, the supervising adult should oversee insertion and removal of the devices and should monitor the patient for signs of any of the following.

1. In rare instances, patients may experience an allergic reaction (for example, tingling, swelling, itching, hives, or difficulty breathing) to the polyamide-12 material in the expanders or holders.
2. In rare instances, patients may have undiagnosed hereditary angioedema (HAE) (a genetic disorder in which mild stimuli, including dental procedures, can trigger rapid local swelling of subcutaneous tissues including the larynx).
3. Patients may accidentally swallow or aspirate the device or pieces of them leading to potential injury.
4. Invisalign Palatal Expander System should not be used for treatment of respiratory disorders, sleep apnea, jaw advancement remodeling, and/or temporo-mandibular disorders (TMD). If the devices are not used as intended, serious complications (including chronic pain, tooth dislocation, damaged gums, exposed roots, bone erosion, and tooth loss) may occur, requiring medical intervention.

**If any of the above occurs, please discontinue use, seek medical attention immediately as necessary, and notify the treating doctor at your earliest convenience.**

## PRECAUTIONS

1. Your doctor will consider a number of factors to determine whether the Invisalign Palatal Expander System is the right expansion device for you, when to start treatment with the device, and whether additional interventions or treatments may be appropriate. Before beginning treatment, your doctor will review your chronological and dental age, growth, and the condition of your teeth (including any restorations), palate and jaws in order to assess your overall skeletal and dental maturity.
2. If you have had recent palatal expansion or other orthodontic treatment, your doctor may provide you with a retainer or other appliance following your intraoral scan to ensure that your dentition remains stable and to minimize relapse and shifting prior to delivery of the Invisalign Palatal Expanders.
3. For some patients, particularly adults, undesired tooth movement (for example, molar tipping, in which your molar teeth tip or angle away from their normal upright position) and tooth dislocation may occur during expansion treatment.
4. Atypically shaped, erupting, and/or missing teeth may affect the fit of the device and the efficacy of the treatment.
5. Extended excessive heat exposure could damage the device and impact the proper device fit.
6. If the expanders or holders are worn improperly or are off your palate for an extended continuous period of time, relapse may occur. Failure to wear the devices for the prescribed

- number of hours per day can lengthen the treatment time and could affect the ability to achieve the desired results.
7. Attachments that have been inadequately bonded may fall or shear off before treatment is complete, requiring you to return to the doctor's office promptly for re-bonding.
  8. Attachment bonding could be compromised if 'Stage 0' of expansion or holding phase are not worn as recommended, resulting in debonding of attachment(s) or insufficient device retention and in some instances require replacement.
  9. If you have stainless steel crowns or other restorations, unstable upper first permanent molars, upper second primary molars (or second premolars), and upper first primary molars (or first premolars) or short clinical crowns (less than 4mm) you may not be appropriate for treatment with this device.
  10. Whether or not attachments are bonded to them, existing dental restorations (e.g., crowns and bridges) may become dislodged during expansion treatment, requiring re-cementation or, in some instances, replacement.
  11. A tooth that has been previously traumatized or significantly restored may be aggravated, requiring additional dental treatment.
  12. Dental tenderness and/or tenderness in the palate or jaw (including the 'temporo-mandibular' or jaw joint) may be experienced during treatment. Increased tenderness may occur during initial Invisalign Palatal Expander System placement or when you move to a new active expansion stage.
  13. In rare instances, problems in your temporo-mandibular joint (jaw joint) may occur during treatment and may result in joint pain, headaches, or ear problems.
  14. The health of the bone and gums supporting your teeth may be impaired or aggravated during orthodontic treatment; this may necessitate additional treatment.
  15. The root lengths of your teeth may be shortened during orthodontic treatment, causing a threat to longevity of the teeth.
  16. Soft tissue irritation and discomfort of your palate, gums, cheeks, or lips may occur when using the product.
  17. You may experience tenderness during treatment if you have [a] palatal exostosis (extra growth), surface aberration, cleft palate and/or recession on the buccal aspects of the periodontium.
  18. Your doctor will tell you whether or not you should eat while wearing the device. Eating while wearing the device may lead to complications ranging from device damage to oral infection. You should carefully follow the device use and care instructions and should maintain a careful oral hygiene regimen during treatment.
  19. You may experience some difficulty and discomfort when eating while wearing the device.
  20. Chewing hard, sticky or sugary food (including chewing gum) with the device on may damage the device and/or your teeth and should be avoided. Drinking sugary or acidic drinks with the device on may damage your teeth and should be avoided.

21. Soft foods and small particles may lodge between the device and your palate, increasing the risk of yeast or bacterial infection or fungal infection like oral candidiasis (thrush) and the chance of undesirable device aroma. These risks increase with less frequent expander changes and failure to follow hygiene care instructions.
22. Tooth decay, periodontal disease, and permanent markings from stains and allergies may occur if you do not follow hygiene care instructions during treatment.
23. Wearing this device may temporarily affect your speech and may result in a lisp or other speech impediment, although this should go away over time.
24. Your 'bite' (the way your teeth come together) may change and feel strange or uncomfortable during and at the end of treatment.
25. You may notice a temporary increase in salivation or dryness of the mouth during treatment.

#### RISKS AND BENEFITS OF THE TREATMENT

The risks of treatment with the Invisalign Palatal Expander System are described above in the Warnings and Precautions sections above. The benefit of treatment with this device is that with proper use, it can expand your narrow 'maxilla' (palate, dental arch, upper jaw) to a more optimal state as determined by your doctor. If you have questions about the risks and benefits of Invisalign Palatal Expander treatment, please contact your doctor.

#### IMPORTANCE OF THE NEED TO ADHERE TO A CARE REGIMEN

Failure to wear the devices for the number of hours per day prescribed by your doctor can lengthen the treatment time and affect the ability to achieve the desired results.

Wearing the device for prescribed number of hours, periodic monitoring by your doctor, as well as following guidance for proper oral hygiene and device care is important to achieve the desired results.

#### WEARING YOUR INVISALIGN PALATAL EXPANDERS AND HOLDERS

##### Always remember to:

1. Follow your doctor's instructions and the illustrated directions in this guide to make sure you're inserting and removing your expanders and holders properly. **For minor patients, an adult should supervise the insertion and removal of the devices.**
2. Wear your expanders and holders for the number of hours each day as prescribed by your doctor. Not wearing the device for a continuous extended period of time may cause relapse (your palate moving back to or toward its original position).
3. Wash your hands thoroughly with soap and water before handling your devices.
4. Brush and floss teeth before insertion and after removal of the devices.
5. Clean and rinse your devices when removing them from the packaging. Prior to storing the device in the bag, shake off/pat dry any excess water.
6. Handle only ONE device at a time.

**Take care of your expanders and holders**

1. Both you and the adult who's helping you should check the device each day before you insert it and again at bedtime for any damage or flaws.
2. Be careful when inserting or removing your expanders and holders. Do not use excessive force to bend or twist them, and do not use a sharp implement to try to remove them.
3. If a device appears to be damaged or broken, if you can't insert it, or if it feels like it's not fitting properly (it causes you sharp pain or is extremely uncomfortable), discontinue use and contact your doctor.
4. Keep these devices away from harsh chemicals. Do NOT use denture cleaners or mouthwash to clean your expanders or holders. These products can damage and weaken your devices.
5. Your doctor will bond 'attachments' to your teeth to help keep your expanders in place. If an attachment falls off, please contact your doctor.
6. To avoid damaging the devices and your teeth, do not chew hard or sticky food, chew gum, or drink sugary or acidic drinks while wearing your expanders or holders.
7. Remember to brush and floss your teeth every day before you insert and whenever you remove the device. Failing to take proper care of your teeth during treatment could result in tooth decay, gum disease, and permanent staining on your teeth. See below for more detailed instructions on how to take care of your teeth during treatment.

**Note:** Dental restorative materials made from metal (e.g., amalgam filling or stainless-steel crowns) may cause device discoloration.

**Understanding your new expanders and holders**

1. Your new expanders and holders are designed to be worn day and night, as directed by your doctor. The devices may be worn while you eat and drink, but your doctor may instruct you to remove the devices when you eat. As a reminder, you should not eat hard or sticky foods, chew gum, or drink anything sugary or acidic while wearing the devices.
2. You will change your expanders daily or as directed by your doctor. Do not discard your old expanders; after use, please clean each device, shake off/pat dry any excess water and place in its original bag in case your doctor asks you to reinsert it. For example, if relapse occurs or if one of your expander stages is damaged.
3. Failure to wear the devices for the prescribed number of hours per day can lengthen your treatment time and affect the ability to achieve the desired results.
4. If your doctor decides that additional expanders are needed, the doctor may need to take new digital scans of your teeth and palate.
5. Your doctor will determine when you are ready to move from the active expansion phase to the holding phase. Depending when this happens, you may have some unused expanders left over (these are expansion stages the doctor decided were unnecessary based on your treatment progress). Your doctor may ask you to wear a single expander stage for more than one day to hold your palate in position while you await your holders.

6. Once you switch from the expansion to the holding phase, you will wear each holder for 2 to 4 weeks, as directed by your doctor. The holding phase may vary in duration, depending on your doctor's goals for your treatment. The holding phase prevents relapse; your doctor may also intend this phase to stabilize your expansion treatment before you start the next phase.
7. Once the holding phase is complete, you should continue to wear your holder as directed by your doctor until you start your next phase of treatment.
8. Your expanders and holders are cleaned and individually packaged in labeled pouches (bags) prior to delivery. Each device is imprinted with a unique number which includes certain tracking information for your doctor as well as the expander or holder stage number. Device stages should be worn sequentially. Make sure to wear the devices in the correct order.
9. On the upper right corner of each bag label, you will find the expander or holder stage number marked as 'XX of YY' (for example, '03 of 28'). On the device itself, the matching two-digit device stage ('03' from the example) can be found toward the end of the imprinted number. Once you have completed each stage, clean the device as instructed below, then store it in its original matching bag.

**DEVICE CARE AND STORAGE**

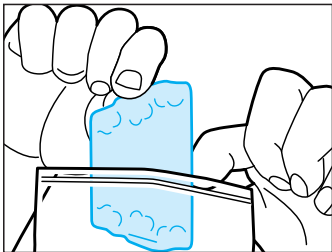
- Use a soft bristle toothbrush with water and a small amount of toothpaste to clean your expanders and holders. Make sure to remove all toothpaste by thoroughly rinsing the device after cleaning.
- Always store devices in a cool and dry place.
- We recommend that you store your device in its original bag whenever it's not in your mouth. This will help protect it from loss and damage.
- Clean and thoroughly dry the device before you store it in the bag.
- Keep the devices out of reach of small children and pets.

**PROPER ORAL HYGIENE**

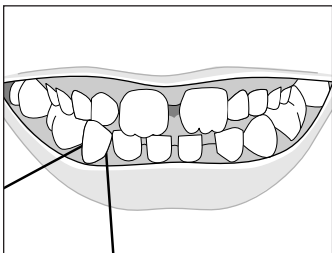
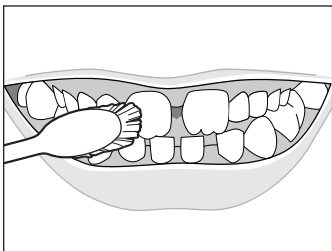
- You do not need to remove your devices for eating or drinking. However, it is recommended to rinse the mouth thoroughly after each meal.
- Brush and floss your teeth before you insert the device. If you don't have access to your toothbrush, you can simply rinse your mouth, and then clean your devices by holding them under running water. It's not the best way to clean, but it works in a pinch. Be sure to thoroughly clean your devices and your teeth at your earliest convenience.
- If you have any questions regarding hygiene techniques, please consult your doctor.
- Regular dental checkups and cleaning are recommended throughout treatment for the continued health of your teeth and gums.

**INSTRUCTIONS FOR DEVICE INSERTION**

1. Remove the device from the small bag that it came in. Do not throw away the original bag as it will be used to store the used devices.

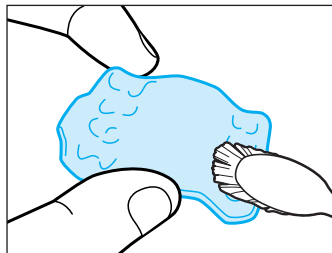


2. Ensure to brush and floss teeth before the device insertion.

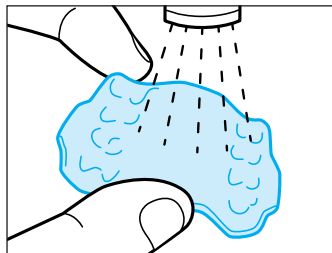


3. Confirm stage number by referencing "Understanding your new expanders and holders" section.

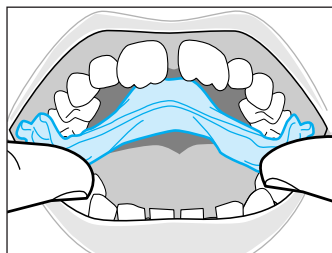
4. Before the device insertion:
  - Clean the device with a soft bristle toothbrush, water, and a small amount of toothpaste.



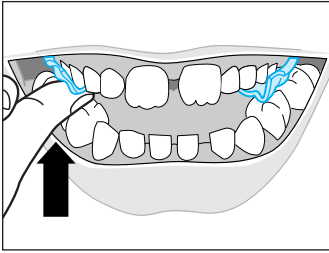
- Rinse the device thoroughly with running water.



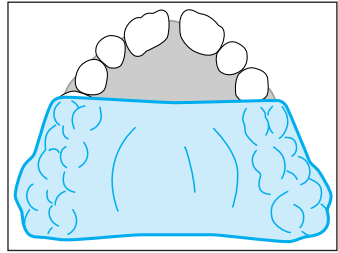
5. Place the device in the mouth under the upper back teeth, directly above the attachment wells.



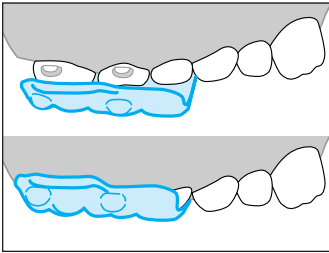
6. Push the device upward with a thumb or index finger until one side of the device is fully engaged.



pressing up on the buccal surface of the device with a finger.

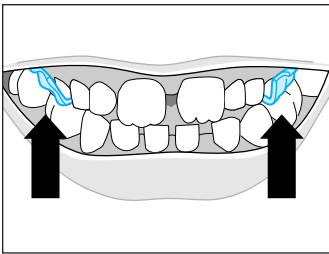


- The attachment wells of the device must be seated on the



attachments.

7. Once the device is engaged on one side, remove the thumb

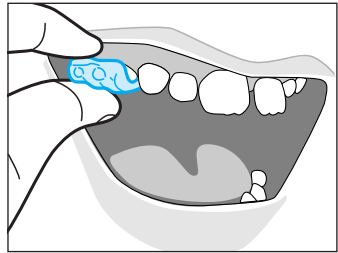


or index finger used to push the device upward.

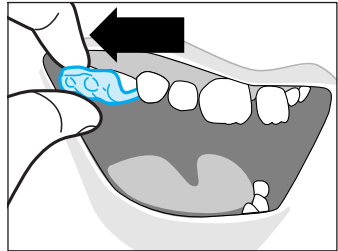
- Bite down to engage the device on the opposite side.
- If biting down alone does not fully engage the device, then try biting down on an aligner seater or biting down while

8. The device should now be fully seated. Inspect for proper fit of the device.

#### INSTRUCTIONS FOR DEVICE REMOVAL

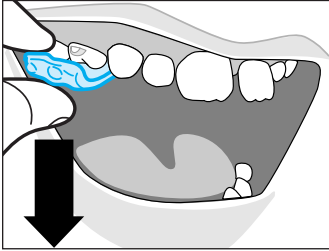


1. On one side of the device, place finger or thumb on top



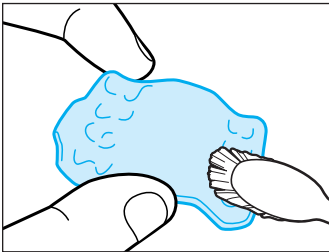


of removal handle. Another finger or thumb may be placed



on the bottom surface of expander for better control.

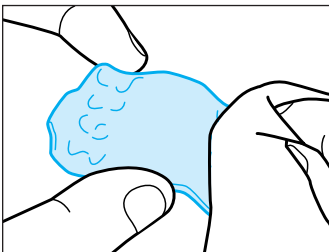
2. Pull out toward the cheek to disengage from the attachment.
3. Pull down the device to remove it.



4. After the device removal:

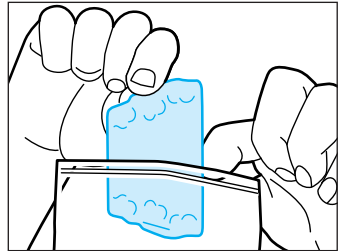


- Clean the device with a soft bristle toothbrush,



water and a small amount of toothpaste.

- Rinse the device thoroughly with running water.



- Wipe the device with a tissue so that's its dry.

5. Do not throw away the used device. Store the device in its original bag.

**Note:**

- Immediately clean the device with toothpaste, toothbrush and water, thoroughly rinse and dry the device store it in its original bag.
- Take care in removing your expanders and holders.
- Do NOT use excessive force to bend or twist a device to get it off.
- Do NOT use any sharp object to remove your devices.
- Consult with your doctor if your devices are extremely difficult to remove.

**CUSTOMER INFORMATION/USER INFORMATION**

In case of a serious incident that directly or indirectly led, might have led or might lead to any of the following: a) the death of a patient, user or other person, b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, c) a serious public health threat please immediately without any delay inform Align Technology and your health care professional.

**DEVICE DISPOSAL**

After your doctor confirms your treatment is complete, the Invisalign Palatal Expanders and Invisalign Palatal Holders should be disposed of in compliance with national and local laws.

**FREQUENTLY ASKED QUESTIONS AND ANSWERS**

**Q: What if I lose or break one of my expanders or holders?**

**A:** In the event that a device is lost or broken, you should immediately contact your doctor. Your doctor will probably tell you to start wearing your previous set or next set of devices immediately. He or she may order you a new set of devices (which should arrive in a few days) to replace the ones you just lost.

**Q: Why did the doctor attach bumps to some of my teeth?**

**A:** Bumps or "attachments" are bonded [i.e. glued] to help the device grip the teeth and aid with expansion. Devices have attachment wells or pockets that grip the bumps or "attachments" the doctor places on your teeth. The attachments are actually small pieces of composite or dental tooth colored material the doctor affixes to your teeth that are then gripped by attachment wells or pockets on your devices.

**Q: Will the treatment be painful?**

A: Most people experience soreness and pressure after starting each new stage. This is normal. It is a sign that the devices are working, expanding your palate to the desired position.

**Q: Will wearing the Invisalign Palatal Expander System devices affect my speech?**

A: Like all orthodontic treatments, the device may temporarily affect your speech, and you may have a slight lisp for a period of time. However, as your tongue and palate get used to having devices in your mouth, any lisp or minor speech impediment caused by your devices should resolve.

**Q: What should I do if my new Invisalign Palatal Expander system device doesn't snap onto my teeth?**

A: Minor fit differences between the new device and the current tooth position are normal, since the teeth need time to conform to the new device position. In the event of significant problems with the device fit, inform your doctor.

**Q: Are there restrictions on what I can eat?**

A: Chewing hard, sticky or sugary food (including chewing gum) with the device on may damage the device and/or your teeth and should be avoided. Drinking sugary or acidic drinks with the device on may damage your teeth and should be avoided.

**Q: How should I clean the device?**

A: You should not put the device in boiling water or the dish washer, or use any over the counter orthodontic cleaning product to clean the device. Only use toothbrush and toothpaste.

**Q: Can I chew gum while wearing the Invisalign First Palatal Expander system devices?**

A: NO. Gum will stick to the devices and should be avoided.

**Q: Will smoking, vaping or chewing tobacco stain the Invisalign Palatal Expander System devices?**

A: We discourage tobacco and vaping use while wearing the devices because of the possibility of discoloration or damage.

**Q: What if I lose or break an attachment?**

A: In the event that an attachment is lost or broken, you should immediately contact your doctor.

**Q: Who should I call if I still have questions about this product?**

A: Please contact your doctor first. If you have any additional inquiries, you can call Align Technology, Inc. customer care at 1-888-822-5446 for assistance.

**Note:** If you have additional questions after reading this pamphlet, please consult with your doctor.

**SYMBOLS GLOSSARY**

Symbol	Title	Explanatory text	Standard reference
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	EN ISO 15223-1*, 5.4.3
	Country of manufacture	To identify the country of manufacture of products. In the application of this symbol, the "CC" shall be replaced by either the two-letter country code or the three-letter country code defined in ISO 3166-1. The date of manufacture may be added adjacent to this symbol.	EN ISO 15223-1*, 5.1.1
	Patient name	Indicates the name of the patient.	EN ISO 15223-1*, 5.7.2
	Patient number	Indicates a unique number associated with an individual patient.	EN ISO 15223-1*, 5.7.1
	Manufacturer	Indicates the medical device manufacturer.	EN ISO 15223-1*, 5.1.1
	Date of manufacture	Indicates the date when the medical device was manufactured.	EN ISO 15223-1*, 5.1.3
	Single patient multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.	EN ISO 15223-1*, 5.1.12
	Lot number/batch number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN ISO 15223-1*, 5.1.5
	Medical device	Indicates the item is a medical device.	EN ISO 15223-1*, 5.7.10
	Catalogue number	Indicates the manufacturer's catalog number so that the medical device can be identified.	EN ISO 15223-1*, 5.1.6
	Unique device identifier	Indicates a carrier that contains unique device identifier information.	EN ISO 15223-1*, 5.7.10
	Keep away from direct sunlight and heat	Indicates a medical device that needs protection from light sources and heat.	EN ISO 15223-1*, 5.3.2
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for Use for additional information.	EN ISO 15223-1*, 5.2.8
	Keep dry	Indicates a medical device that needs to be protected from moisture.	EN ISO 15223-1*, 5.3.4
	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.	US Code of Federal Regulations, Title 21, Part 801.109(b)(1)

\*Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.

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